Individualization with composite stain

Commercially available composite stain materials (e. g. VITA ENAMIC STAIN*, Vita Zahnfabrik and GC OPTIGLAZE Color*, GC) can be used for individualization of the post-cured SprintRay Crown restoration. The manufacturer's instructions for use must be observed.

Individualization with veneering materials

Commercially available composite veneering materials (e. g. VITAVM LC*, Vita Zahnfabrik and VITAVM LC flow*, Vita Zahnfabrik) can be used for individualization of the restoration. The manufacturer's instructions for use must be observed

Veneer shells

Commercially available light-curing veneering composites can be used to attach the post-cured veneer shells to the metal framework (e. g. VITAVM LC, VITAVM LC flow, Vita Zahnfabrik). When designing and preparing the metal framework and processing the veneering material, the instructions for use of the veneering material manufacturer must be observed.

Basic work steps

- Condition the surface of the metal framework.
- Cover the metal framework with opaquer.
- Sandblast the inside of the veneer shell and clean the veneer shell from dust.
- Inner surface conditioning of the veneer shell. Observe the information of the veneering material manufacturer in section "Individualization of composite frameworks" or "Individualization of artificial teeth".
- Applying the veneering material to the inside of the veneer shell or the metal framework.
- Positioning of the veneer shell on the metal framework and remove the excess with a brush or an instrument.
- Carry out the polymerization according to the instructions of the veneering material manufacturer.
- Finally, the surface of the veneer shell should be polished or customized with composite stains (see section "Polishing" or "Individualization")

8. Cleaning in the dental laboratory and dental practice Fully cured objects made from SprintRay Crown may be cleaned and disinfected. Steam cleaning (e. g., with Triton SLA) is possible. Disinfection in the immersion bath (e. g. ethanol 96 % or MD 520* impression disinfectant, Dürr Dental Co.) is also possible.

Follow manufacturer's instructions.

9. Luting

Cementation on abutments

The definitive restoration can be fixed onto titanium abutments (e. g. BEGO Semados® solid titanium abutments) with Panavia v5 (Kuraray Noritake*). The instructions for use of the luting agent manufacturer must me observed.

Attachment to tooth stump

The finished permanent restorations can be attached using self-adhesive cements (e. g. RelyX Unicem*, 3M Espe) or composite cement with a primer (e. g. Variolink Esthetic DC* and Monobond Plus*, Ivoclar Vivadent). Observe the instructions for use of the luting agent.

Note for practitioners

- Restorations can undergo high-gloss polishing with composite polishers commonly used in dental practice.
- Observe the instructions for use of the luting agent. It is not required to etch the restoration before attaching.
 Additional exposure to curing lights after attachment will
- not affect the properties of the finished object.

10. Disposal

The cured, separated material (base plate, support structure) can no longer be used. Cured material can be disposed of as

11. Material properties and scope of delivery

Physical data

Colour*,** Viscosity* 2,500-6,000 A1 Dentin A2 Dentin A3 Dentin B1 Dentin B2 Dentin C2 Dentin D3 Dentin Flexural strength** ≥ 100 MPa Density 1.4-1.5 g/cm³

* applies to liquid resin ** applies to cured objects



REF Catalogue number

Keep away from sunlight

LOT Batch code



!\ Caution

SprintRay Crown

en Instructions for use

SprintRay

Visit support.sprintray.com Call +1 (800) 914-8004 SprintRay Inc. USA 2705 Media Center Dr, Los Angeles, CA 90065

E-Mail: info@bego.com · www.bego.com Wilhelm-Herbst-Str. 1 · 28359 Bremen, Germany Tel. +49 421 20 28-0 · Fax +49 421 20 28-100 BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG



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en Instructions for use

Resin for 3D printing of permanent single crowns, inlays onlays and veneers. SprintRay Crown is used within a dental CAD/CAM workflow and should only be used with compatible 3D printers and post-curing devices. Section 6. below includes a list of requirements for the use of this device.

CAUTION: Federal law restricts this device to sale by or on the order of a dentist. For professional use only - Rx Only

SprintRay Crown is a light-cured, methacrylate-based resin used in 3D printers for the production of permanent crowns, inlays, onlays and veneers. SprintRay Crown is suitable for restoration of occlusal surfaces

SprintRay Crown is cured externally to the patient by light sources within the 3D printer and the post-curing device described below.

1. Indications for Use

SprintRay Crown is indicated as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces. The SprintRay Crown material is used for fabricating permanent restorations such as inlays, onlays, veneers and full crown restorations.

2. Contraindications

Known allergy to one or more ingredients. In cases of doubt, the allergy should be clarified and ruled out based on a specific test prior to the application of this product. SprintRay Crown should not be used for purposes other than the production of permanent single crowns, inlays, onlays and veneers. Any deviation from these instructions for use can have negative effects on the chemical and physical quality of objects made from SprintRay

3. Safety instructions SprintRay Crown is produced and tested according to the stringent quality standards. In order to ensure optimum further processing, please read the information contained in the instructions for use carefully. The improper use of SprintRay Crown and failure to follow information can have a detrimental effect on the quality of objects produced from SprintRay Crown 3D resin. Nitrile gloves, safety goggles and a coat must be worn as a means of protection when handling the resin and the object that has not been post-cured. Conventional medical gloves do not offer any lasting protection against the sensitising effect of methacrylates. If the product comes into contact with the glove, take the glove off and discard it, wash your hands immediately with water and soap and put on a new glove. Consult a physician in the event of an allergic reaction.

The safety and care instructions set down in the SprintRay Crown instructions for use and safety data sheet shall apply to the handling of liquid resin and printed objects that have not been post-cured (objects in the "green condition"). A dust mask must be worn too due to potential dust formation while the printed objects are being processed.

4. Side effects and precautions

Precautions / Protection
Protective clothing should be worn when handling un-cured SprintRay Crown. Safety goggles and nitrile gloves must be used. Further information on handling the product can be found in the safety data sheet and also downloaded at www.sprintray. com. However, we cannot completely rule out the possibility of personal reactions to individual components in isolated cases. In such cases, the respective user should discontinue use of SprintRay Crown.



DANGER

Information on hazards as per MSDS

- Causes skin irritation
- May cause an allergic skin reaction. Causes serious eye irritation.
- May cause respiratory irritation
- May damage fertility or the unborn



DANGER

Safety instructions as per MSDS Prevention

Obtain special instructions before use.

- Do not handle until all safety precautions have been read and understood.
- Avoid breathing dust.
- Wash thoroughly after handling.
 Use only outdoors or in a well-ventilated
- Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves / protective
- clothing / eye protection / face protection.

Response If on skin: Wash with plenty of water

- and soap · If inhaled: Remove person to fresh air
- and keep comfortable for breathing. · If in eyes: Rinse cautiously with water
- for several minutes. Remove contact lenses, if present and easy to do Continue rinsing. · If exposed or concerned: Get medical
- advice / attention. • Call a poison center / doctor if you feel
- unwell.
- Specific treatment (see first aid instruction on this label)
- · If skin irritation occurs: Get medical advice / attention.
- Take off contaminated clothing and wash it before reuse.
- Wash contaminated clothing before

Storage · Store in a well-ventilated place. Keep

container tightly closed.

- Store locked up
- Disposal

Dispose of contents / container to a

facility in accordance with local and national regulations

Patient precautions

If intolerances or allergic reactions occur when it comes into contact with the patient, discontinue use of the material.

5. General information on handling

SprintRay Crown is supplied in seven colours according to the VITA* classical shade system, in lightproof and sealed bottles. Filling quantity

- SRI-0205040 = SprintRay Crown A1, 500g

- SRI-0205041 = SprintRay Crown A2, 500g SRI-0205042 = SprintRay Crown A3, 500g SRI-0205043 = SprintRay Crown B1, 500g
- SRI-0205044 = SprintRay Crown B3, 500g SRI-0205045 = SprintRay Crown C2, 500g SRI-0205046 = SprintRay Crown D3, 500g

Note: The availability of individual product variants may vary from region to region. The latest product information can be found on the SprintRay website.

Storage

SprintRay Crown must be stored in the original sealed bottle, or in the resin tank at room temperature (approx. 22 °C) in a dark, dry place. Unused resin in the resin tank has to be stored in the closed printer which protects the resin from light, or in an alternative dark, dry location. It must be ensured that the temperature does not drop below +4 $^{\circ}\text{C}$ and does not exceed +28 °C! The minimum shelf life date printed on the product must be observed.

CAUTION: Expected results cannot be guaranteed if materials which have exceeded their minimum shelf life date are used or if storage instructions are not followed.

The completely cured print objects must be stored at room temperature and protected from sources of light.

6. Processing requirements 1. Design

- Create the object (STL-file) using a commercial CAD software, which is intended for dental applications.
- The design must match the anatomical dimensions of the tooth to be restored.
- The ratio of the crown height to the height of the bonding surface of the abutment must not exceed a value of 1.6.
- When designing, observe the requirements for minimum wall thicknesses for finished restorations

Crowns, inlays, onlays and veneers

	Minimum wall thicknesses anterior teeth	1.0 mm
	Minimum wall thicknesses posterior teeth	1.0 mm
	Minimal wall thickness, cervical	1.0 mm
	Minimal wall thickness, veneer shell	0.5 mm

2. Nesting & preparation for printing

- Import STL file
- Manual / Automatic rotation and placement
- Optimal orientation: horizontal, occlusal plane facing the build platform
- Automatic generation of supports

3. Printing

SprintRay Crown has been verified and validated in combination with various system components (3D printers, cleaning devices and post-curing devices). We are constantly working on further qualifications. You can find these compatible sys

tem components on our website https://sprintray.com/sprintray-open-certified-resin-system/#list Please pay special attention to the build platform and resin tank materials as noted in the compatibility matrix.

An example list of compatible 3D additive manufacturing printers and their operation software:

Compatible 3D Printers

3D Printer Model	Wave- length	Printer Firmware	Nesting Software	Provider
SprintRay Pro 55	405 nm	6.5 or higher	RayWare	SprintRay
SprintRay Pro 95	405 nm	6.5 or higher	RayWare	SprintRay



WARNING: This material is suitable for manufacturing highly reliable dental products only when using approved compatible systems including the material parameters. If unapproved components or material parameters are used, there is a high risk of unreliable and/or unusable products which may endanger the safety of the user CAUTION: It is important to follow the instructions for use

for selecting the correct material program and maintenance instructions provided by the manufacturer for all system com-

Environmental Conditions

Temperature range between 18 °C and 28 °C

- Layer thickness: 50 µm Optimal orientation: horizontal orientation, occlusal plane
- facing the build platform. 4. Necessary tools, equipment and materials for

post-processing Stainless steel spatula Unheated ultrasonic bath

- Ethanol solution 96 %
- Spray bottle with 96 % ethanol solution Cutting wheel or side cutters (for support structure removal)
- Sandblaster 1.5 bar
- Glass bead blasting material 50 μm (e. g. BEG0 Perlablast $\!^{\circ}$ micro)

7. Processing The following instructions contain details of a validated work-

flow for the 3D printing process with a compatible 3D printer. The ideal working temperature of SprintRay Crown is in the temperature range between 18 °C and 28 °C. Before use, the resin must be homogeneous. Before the first

use, the material has to be shaken well about 2 min. When decanting, make sure that the printing resin is exposed to daylight for as short a period of time as possible. Mix the resin in the cartridge / resin tank if a transparent layer is visible on the surface

CAUTION: The device specifications have been validated using the software, printers, and process parameters specified in this document. Any unauthorized changes to the process equipment, parameters, or software may result in a device that is out of specification and not covered under the FDA clearance. Users shall follow this document in order to use the SprintRay Crown. Users shall also follow the instructions for use documents and all maintenance requirements for the equipment identified in this document.

Cleaning and preparation for post-curing

On completion of printing, the print objects are released from the build platform using the spatula. The print object should be cleaned in two steps with ethanol (96 %) using an ultrasonic bath. For additional cleaning devices and methods refer to https://sprintray.com/sprintray-open-certified-resin-system/#list CAUTION: Never fill ethanol directly into the ultrasonic bath;

place it in the recommended container in the ultrasonic bath filled with water. Use an explosion-proof ultrasonic bath. 1. Clean the print object for 3 min in a reusable ethanol solu-

- tion (96 %) using an unheated ultrasonic bath.
- 2. The precleaned object must be cleaned thoroughly for **2 min** using a fresh ethanol (96 %) solution with the aid of an **un**heated ultrasonic bath.
- 3. The print object is then removed from the ethanol bath and sprayed with additional ethanol (96 %) in order to fully rinse off any remaining resin residue.

Tip: Resin residues can also be removed using a brush soaked in ethanol (96 %)

CAUTION: The entire cleaning process should not take longer than 5 min as this could otherwise have a detrimental effect on the printed objects (swelling of the object with ethanol). After cleaning, the print object is dried using compressed air under an extraction unit. If there is liquid resin still adhering to

the surface of the object, this can be completely removed by spraying again with ethanol (96 %) and re-drying. Preparation for post-curing Remove the support structure with the help of a cutting

- wheel or side cutters.
- Sandblast the surface of the objects carefully with BEGO Perlablast® micro and at a maximum blasting pressure of
- Check for fit and finish the objects completely. Finishing and countouring can be performed using carbide cutter or diamond grinding stones.

Post-curing process

The final properties of the printed object depend on the post-curing process. Please note the assignment of the light curing device to the 3D printer of the approved system com-

The post-curing of the object is done without use of a model, followed by cooling time until object is cool to the touch (3 – 5 minutes) SprintRay Crown has been verified and validated in combina-

tion with various system components (3D printers, cleaning devices and post-curing devices). You can find these compatible system components on our website https://sprintray.com/sprintray-open-certified-resin-system/#list An example list of compatible post-curing devices:

Post-curing

Light-curing device	Program
SprintRay ProCure	Select SprintRay Crown program
SprintRay ProCure 2	Select SprintRay Crown program



WARNING: This material is suitable for manufacturing highly reliable dental products only when using approved compatible systems including the material parameters. If unapproved components or material parameters are used, there is a high risk of unreliable and / or unusable products which may endanger the safety of the user

Note: The times given only apply to regularly maintained equipment that guarantees a corresponding light intensity.



CAUTION: If there is an interruption or failure in the post-curing device cycle, the printed object should not be used until it has cured under a full cycle. Check the post-curing device manual for use for how to properly resolve the post-curing device condition and then repeat the post-curing cycle with the printed objects.

Supplementing of printed objects

Defects (e. g. missing contact points, fractures, etc.) can be supplemented with the resin or with commercially available composite veneering materials.

- Blast the areas to be supplemented with aluminum oxide
- pressure 1.5 bar and particle size 110 μm. Put some liquid SprintRay Crown on the object.
- Put it under UV-light for a short time.
- If more material has to be applied, put additional liquid SprintRay Crown on the last layer and then put it again under UV-light for a short time.
- Final curing of the objects is carried out as described in the section "Post-curing process" (see table).

Supplementing with veneering material

The printed objects can be supplemented with commercially available composite veneering materials (e. g. VITAVM LC*, Vita Zahnfabrik, and VITAVM LC flow*, Vita Zahnfabrik). The manufacturer's instructions for use must be observed CAUTION: The dental object may only be repaired or sup-



plemented outside the patient's mouth and by a dental professional. Polish Polish the surface of the objects with pumice stone and

during polishing. Optimal surface quality is achieved by pol-

compound. Avoid overheating of the

Tip: Optionally, the surface of the objects can be coated with light-curing glaze (e. g. Vita ENAMIC GLAZE *, Vita Zahnfabrik or GC OPTIGLAZE *, GC). Pay attention to the manufacturer's instructions for use. Individualization (optional)

ishing after post-curing.

Instead of polishing the surface, the post-cured objects can also be individualized with composite stains or veneering materials. It may affect the color result.

mate, diphenyl(2,4,6 tri-methylbenzoyl phosphine oxide. Overall share of inorganic Fillers (par ticle size 0.7 µm) totals 30-50% by mass.

sterification products

ized dental glass,

of 4,4'-Isopropylidi-phenol, ethoxylated

and 2-methyl

prop-2enoic acid