

VarseoSmile Crown^{plus}

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Instructions for use

VarseoSmile Crown^{plus}

Resin for 3D printing of permanent single crowns, inlays, onlays and veneers. VarseoSmile Crown^{plus} 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.

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

VarseoSmile Crown^{plus} is cured externally to the patient by light sources within the 3D printer and the post-curing device described below.

1. Indications for Use

VarseoSmile Crown^{plus} is indicated as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces. The VarseoSmile Crown^{plus} 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. VarseoSmile Crown^{plus} 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 VarseoSmile Crown^{plus}.

3. Safety instructions

VarseoSmile Crown^{plus} 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 VarseoSmile Crown^{plus} and failure to follow information can have a detrimental effect on the quality of objects produced from VarseoSmile Crown^{plus} 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 VarseoSmile Crown^{plus} 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 VarseoSmile Crown^{plus}. 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 from the BEGO Download Centre at www.bego.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 VarseoSmile Crown^{plus}.



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 child.



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 area.
- 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 reuse.

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

Contains:
sterification products of 4,4'-Isopropylidenediphenol and 2-methylprop-2-enoic acid, silanized dental glass, methylbenzoylformate, diphenyl(2,4,6-trimethylbenzoyl) phosphine oxide.
Overall share of inorganic fillers (particle size 0.7 µm) totals 30–50% by mass.

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

Delivery

VarseoSmile Crown^{plus} is supplied in seven colours according to the VITA* classical shade system and one BEGO Bleach Shade, in light-proof and sealed bottles.

Filling quantity:

- REF 41107US = 500 g, A1 Dentin
- REF 41117US = 250 g, A1 Dentin
- REF 41108US = 500 g, A2 Dentin
- REF 41118US = 250 g, A2 Dentin
- REF 41109US = 500 g, A3 Dentin
- REF 41119US = 250 g, A3 Dentin
- REF 41110US = 500 g, B1 Dentin
- REF 41120US = 250 g, B1 Dentin
- REF 41111US = 500 g, B3 Dentin
- REF 41121US = 250 g, B3 Dentin
- REF 41112US = 500 g, C2 Dentin
- REF 41122US = 250 g, C2 Dentin
- REF 41113US = 500 g, D3 Dentin
- REF 41123US = 250 g, D3 Dentin
- REF 41114US = 500 g, BL Dentin
- REF 41124US = 250 g, BL Dentin

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

Storage

VarseoSmile Crown^{plus} must be stored in the original sealed bottle, or in the cartridge 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 °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

a. 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

b. 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

c. Printing

VarseoSmile Crown^{plus} 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 system components on our website

<https://usa.bego.com/3d-printing/compatibility-overview/>
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
Varseo	405 nm	1.14 or higher	BEGO	BEGO
Varseo L	405 nm	1.02 or higher	CAMCreatorPrint	
Varseo S	405 nm	1.14 or higher	Version 1.14 or higher	
Varseo XS	405 nm	2.6.8.24 or higher		
ASIGA MAX UV	385 nm	2018-09-03	ASIGA Composer	ASIGA
SprintRay Pro 55	405 nm	6.32.5	RayWare	SprintRay
SprintRay Pro 95	405 nm	2.5.1	RayWare	SprintRay



WARNING: This material is suitable for manufacturing highly reliable dental products only when using BEGO 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 and maintenance instructions provided by the manufacturer for all system components

Environmental Conditions

- Temperature range between 18 °C and 28 °C

Printing Parameters

- Layer thickness: 50 µm
- Optimal orientation: horizontal orientation, occlusal plane facing the build platform.

d. 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. Perlablast® micro, REF 46092/54302)

7. Processing

The following instructions contain details of a validated workflow for the 3D printing process with a compatible 3D printer.

The ideal working temperature of VarseoSmile Crown^{plus} 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 VarseoSmile Crown^{plus}. Users shall also follow the instructions for use documents and all maintenance requirements for the equipment identified in this document.

* This symbol is a commercial designation/registered trademark of a company that is not part of the BEGO company group.

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://usa.bego.com/3d-printing/compatibility-overview/>

CAUTION: Never fill ethanol directly into the ultrasonic bath; place it in the recommended container (REF 19621) 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 solution (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 **unheated** 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 Perlablast® micro (REF 46092/54302) and at a maximum blasting pressure of 1.5 bar.
- Check for fit and finish the objects completely. Finishing and counter-touring 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 components.

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).

VarseoSmile Crown^{plus} has been verified and validated in combination with various system components (3D printers, cleaning devices and post-curing devices). You can find these compatible system components on our website

<https://usa.bego.com/3d-printing/compatibility-overview/>

An example list of compatible post-curing devices:

Post-curing

3D Printer	Light-curing Device	Exposure Cycles	Additional Information
BEGO Varseo BEGO Varseo L	BEGO-Otoflash	2 x 1,500 flashes	
BEGO Varseo S BEGO Varseo XS	HiLite-Power*	2 x 90 seconds	Turn object between the exposure cycles
ASIGA MAX UV			
SprintRay Pro 55	SprintRay ProCure	2 x 20 min at 20 °C	
SprintRay Pro 95	SprintRay ProCure	2 x 20 min at 20 °C	

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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 VarseoSmile Crown^{plus} on the object.
- Put it under light for a short time (5 flashes) in the BEGO Otoflash
- If more material has to be applied, put additional liquid VarseoSmile Crown^{plus} on the last layer and then put it again under light for a short time (5 flashes) in the BEGO Otoflash.
- Final curing of the Objects by using the BEGO Otoflash for 2 x 1500 flashes or HiLite Power for 2 x 90 s.

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 supplemented outside the patient's mouth and by a dental professional.

Polish

Polish the surface of the objects with pumice stone and polishing compound. Avoid overheating of the restorations during polishing. Optimal surface quality is achieved by polishing after post-curing.

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)

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.

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 VarseoSmile Crown^{plus} 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 VarseoSmile Crown^{plus} 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 be 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 domestic waste.

11. Material properties and scope of delivery

Physical data

Colour*: **	A1 Dentin A2 Dentin A3 Dentin B1 Dentin B2 Dentin C2 Dentin D3 Dentin BL Dentin	Viscosity*	2,500–6,000 mPa*s
Density	approx. 1.4–1.5 g/cm ³	Flexural strength**	≥ 100 MPa

* applies to liquid resin ** applies to cured objects

12. Label symbols

	Manufacturer		Consult instructions for use
	Date of manufacture		Use-by date
	Batch code		Caution
	Catalogue number		Temperature limit
	Keep away from sunlight		For professional use only

* This symbol is a commercial designation/registered trademark of a company that is not part of the BEGO company group.



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