VarseoSmile Crown plus

en Instruction for use

Partners in Progress

BEGO

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.

WARNING

Information on hazards as per MSDS

- Causes skin irritation.
- May cause an allergic skin reaction.
- Causes serious eye irritation.
- May cause respiratory irritation.
- May cause long harmful effects to aquatic life.

Safety instructions as per MSDS

- Avoid breathing mist/vapours/spray.
- Avoid release to the environment.
- Wear protective gloves/protective clothing/eye protection/face protection.
- Call a POISON CENTER/doctor if you feel unwell.
- If skin irritation or rash occurs: Get medical advice/attention.
- If eye irritation persists: Get medical advice/attention.
- Dispose of contents/container as per local and national regulations.

Contains:
Esterification products of 4,4'-isopropylidiphenol, ethoxylated and 2-methylprop-2enoic acid. Silanized dental glass, methyl benzoylformate, diphenyl(2,4,6-trimethylbenzoyl) phosphine oxide. Total content of inorganic fillers (particle size 0.7 µm) is 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.

In performance testing, this restoration material has been shown to be stained by red wine. Discoloration of restorations can be caused by pigmented drinks, including red wine. Patients should be encouraged to brush their teeth regularly or to rinse with water as soon as possible, to minimize staining.

5. General information on handling

Delivery

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

Delivery form				
	Contents	Presentation	Qty	REF
VarseoSmile Crown plus, A1 Dentin	500 g	bottle	1	41107US
VarseoSmile Crown plus, A1 Dentin	250 g	bottle	1	41117US
VarseoSmile Crown plus, A2 Dentin	500 g	bottle	1	41108US
VarseoSmile Crown plus, A2 Dentin	250 g	bottle	1	41118US
VarseoSmile Crown plus, A3 Dentin	500 g	bottle	1	41109US
VarseoSmile Crown plus, A3 Dentin	250 g	bottle	1	41119US
VarseoSmile Crown plus, B1 Dentin	500 g	bottle	1	41110US
VarseoSmile Crown plus, B1 Dentin	250 g	bottle	1	41120US
VarseoSmile Crown plus, B3 Dentin	500 g	bottle	1	41111US
VarseoSmile Crown plus, B3 Dentin	250 g	bottle	1	41121US
VarseoSmile Crown plus, C2 Dentin	500 g	bottle	1	41112US
VarseoSmile Crown plus, C2 Dentin	250 g	bottle	1	41122US
VarseoSmile Crown plus, D3 Dentin	500 g	bottle	1	41113US
VarseoSmile Crown plus, D3 Dentin	250 g	bottle	1	41123US

Please check the following points on receipt of the goods:

- Integrity of the bottle/pack
- Quantity
- Shipping documents and designation

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

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.

6. Processing requirements

Design file/equipment requirements

1. **Digital crown, inlay, onlay or veneer file: STL file format**

2. **Observe minimum wall thickness as follows:**

Single 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

3. **Compatible 3D additive manufacturing printers and their operation software:**
   3.1. Light source wavelength: 405 nm

3D Printer Model	Printer Firmware	Nesting Software	Provider
Varseo	1.14 and above	BEGO CAMCreator Print Version 1.14 and above	BEGO
Varseo L	1.02 and above		
Varseo S	1.14 and above		
Varseo XS	2.6.8.24 and above		

3.2. Environmental Conditions
- Temperature range between 18 °C and 28 °C

3.3. Software: BEGO CAMcreator Print
- STL file import
- Manual / Automatic rotation and placement (parts should be oriented as stated below)
- Manual / Automatic generation of supports
- Optimal orientation: horizontal orientation, occlusal plane facing the build platform

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

4. Recommended post-processing equipment
- Stainless steel spatula
- Unheated ultrasonic bath
- Ethanol solution 96 %
- Spray bottle with 96 % ethanol solution
- Cutting wheel and slow-speed handpiece or side cutters (for support structure removal)
- Sandblaster 1,5 bar
- Glass bead blasting material 50 µm (e.g. Perlablast® micro, REF 46092 / 54302)

5. Compatible post-curing light device

Product Name / Model	Provider	Light Wavelenght Range	Flash Frequency
BEGO Otoflash	BEGO	300 – 700 nm	10 Hz
HiLite Power	Kulzer Dental	390 – 540 nm	20 Hz

Post curing steps are described in “Recommended steps for finishing and post-curing process” in section 7. Processing.

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. Contact BEGO for a list of compatible components.

7. Processing

Before the first filling of VarseoSmile Crown plus into the cartridge/resin tank, vigorously shake the bottle prior to pouring the resin. Minimize exposure of the resin to light during this process. Before starting each printing process, VarseoSmile Crown plus does not need to be mixed, even after long periods of non-use, because solids (fillers) did not settle. If after a long period of non-use there is visible a layer on the surface, mix the resin with the blank card from BEGO (REF 19551) or with a silicone dough scraper until the visible layer has been completely mixed into the resin and no longer visible. Before each print, check for air bubbles between build platform and the bottom of the cartridge. Air bubbles can negatively affect the print result.

Subsequent processing

To start a print job, refer to instructions for use of the compatible printer. Follow the manufacturer's instructions for use for printer set up and case processing. On completion of printing, the print objects are released from the build platform using the spatula supplied. In the event that the printed object does not print properly, (e.g. distorted, unexpected holes, etc.) consult the printer Instructions for Use document for further guidance. The print object should then be cleaned in two steps with ethanol (96 %) using an ultrasonic bath.

Note: 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 minutes 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.

Recommended steps for finishing and post-curing process:

1. Remove support structures. They can be removed using either a cutting wheel or side cutters.
2. Sandblast the surface of the objects carefully with Perlablast micro (REF 46092/54302) and at a maximum blasting pressure of 1.5 bar.
3. Check for fit and finish the objects completely. Finishing and contouring can be performed with carbide cutters or diamond grinding stones.
4. Post-curing of printed objects with BEGO Otoflash or HiLite Power* without without the working model (see table below), followed by cooling time until object is cool to the touch (3–5 minutes).
5. Optional step: individualization of the post-cured objects is possible with composite stains and is the responsibility of the user. It may affect the color result. Follow manufacturer's instructions.
   If this step is not considered, follow the next point.
6. Polish the surface of the objects with pumice stone and polishing compound. Avoid overheating of the resin during polishing. Optimal surface quality is achieved by polishing after post-curing.

The post-curing process is a very important step in post-processing. Post-curing is achieved by light polymerization with the **BEGO Otoflash (two xenon stroboscopic lamps, flash frequency 10 Hz, light spectrum 300–700 nm) or with the HiLite Power*, Fa. Heraeus Kulzer (a xenon stroboscope lamp, flash frequency 20 Hz, light spectrum 390–540 nm)**.

CAUTION: It is imperative to use one of the compatible post-curing devices listed below and follow the recommended cycle. The post-curing process is a critical step to meet the biocompatibility and material performance specifications of the restoration. No substitutions or changes to the process are allowed.

Note: Devices shall be maintained according to the device manufacturer's instructions.

VarseoSmile Crown plus			
Post-curing device	BEGO Otoflash (with protective gas)	HiLite Power*	Comments
Flash	2 x 1,500	–	Turn object between the exposure cycles
Time [seconds]	–	2 x 90	

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

Note: When employing the BEGO Otoflash, use the protective gas function. This results in a further reduction of the already low remaining monomer content. To do so, set the protective gas function to switch position 1. Details can be found in the instruction manual for the post-curing device.

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

8. Storage and transportation of printed objects

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

9. 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.

10. Note for practitioners

Restorations can undergo high-gloss polishing with composite polishers commonly used in dental practice. 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.

11. Disposal

The cured, separated material (base plate, support structure) can no longer be used. Cured material can be disposed of as domestic waste. Unused resin or ethanol used for cleaning with resin residues must be disposed of via the local waste disposal authority or a hazardous waste collection point stating the safety data sheet.

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12. Material properties and scope of delivery

Physical data			
Colour*, **	A1 Dentin, A2 Dentin, A3 Dentin, B1 Dentin, B2 Dentin, C2 Dentin, D3 Dentin	Viscosity*	2.500–6.000 mPa*s
Density*	ca. 1,4–1,5 g/cm³	Flexural strength**	116 MPa

* applies to liquid resin ** applies to cured object

13. Label symbols


Manufacturer


Date of manufacture

Batch code

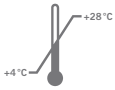
Catalogue number


Keep away from sunlight


Consult instructions for use


Use by date


Caution



Temperature limit

For professional use only

www.bego.com

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