

Instructions for use

VarseoSmile Temp

Resin for 3D printing of temporary crown and bridge restorations, inlays, onlays and veneers.

1. Intended use / Indication for EU / ROW customers

VarseoSmile Temp is a light-curing, free-flowing plastic based on methacrylic acid esters for the production of temporary crowns and bridges, inlays, onlays and veneers.

Intended use / Indication for Canada customers

VarseoSmile Temp is a light-curing, free-flowing plastic based on methacrylic acid esters for the production of temporary crowns and bridges, inlays, onlays and veneers to be used for less than 30 days. The medical device is listed as Class II in Canada, which limits use to 30 days.

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 Temp should not be used for purposes other than temporary crown and bridge work. Any deviation from these instructions for use can have negative effects on the chemical and physical quality of plastics made from VarseoSmile Temp.

3. Safety instructions

This product is produced and tested according to the most stringent quality standards. It may only be used by a dental professional. To ensure optimum further processing, please read the information contained in the instructions for use carefully.

The safety and precautions included in these instructions for use and the 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").

CE 0197

4. Side effects and precautions

Precautions / Protection

It is essential that protective clothing be worn when handling this product. 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. We cannot completely rule out adverse reactions (e. g. intolerance or allergies) to specific material components for all individuals. In such isolated cases, the user should discontinue use of the material.



WARNING

Hazard statements 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.

Contains:
Esterification products of 4,4'-isopropylidiphenol, ethoxylated and 2-methylprop-2enoic acid. Silanized dental glass, methyl benzoylformate, diphenyl (2,4,6-trimethyl-benzoyl) phosphine oxide. Total content of inorganic fillers (particle size 0.7 µm) is 30–50% by mass.

Precautionary statements 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.

Notice: Any serious incident that has occurred in relation to the device due to a malfunction should be reported to the manufacturer and the competent authority of the Member State in which the user and / or patient is established.

5. General information on handling

Delivery

VarseoSmile Temp is supplied in the colours A2 Dentin, A3 Dentin, C2 Dentin, according to the VITA® classical shade system and one BEGO Bleach Shade, in lightproof and sealed bottles.

Filling quantity:

- REF 41022 = 500 g, A2 Dentin • REF 41024 = 500 g, C2 Dentin
- REF 41102 = 250 g, A2 Dentin • REF 41104 = 250 g, C2 Dentin
- REF 41023 = 500 g, A3 Dentin • REF 41026 = 500 g, BL Dentin

- REF 41103 = 250 g, A3 Dentin • REF 41106 = 250 g, BL Dentin

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

Storage

This product must be stored in the original sealed bottle, or in the cartridge at room temperature (approx. 22 °C) in a dark, dry place. 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.

Notice: 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 bright light.

6. Processing requirements

6.1. Design

- Digital crown, bridge, inlay, onlay and veneer file: STL file format

Notice:

- Lifetime of printed restorations is limited for 12 months.
- Max. construction length for bridges 7 units.
- Pontic max. one molar width!
- When designing, observe the requirements for minimum wall thicknesses and connector cross-sectional areas for finished restorations:

Crowns, inlays, onlays and veneers

Minimum wall thicknesses anterior teeth	1.0 mm
Minimum wall thicknesses posterior teeth	1.0 mm

Bridges

Anterior teeth Area	Minimum wall thicknesses crown	1.0 mm
Posterior teeth area	Minimum wall thicknesses crown	1.5 mm
	Minimum cross sectional area of the connector	12 mm ²
	Minimum cross sectional area of the connector	16 mm ²

6.2. Nesting & preparation for printing

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

6.3. Printing

VarseoSmile Temp 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://www.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	Printer Firmware	Nesting Software	Provider
Varseo	1.14 or higher	BEGO	BEGO
Varseo L	1.02 or higher	CAMCreator Print	
Varseo S	1.14 or higher	Version 1.14	
Varseo XS	2.6.8.24 or higher	or higher	ASIGA
ASIGA MAX UV	2018-09-03	ASIGA Composer	



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.

Notice: It is important to follow the instructions for use and maintenance instructions provided by the manufacturer for all system components.

6.4. 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. 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.

VarseoSmile Temp's ideal working temperature 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.

For further processing – selecting the resin, material parameter, setting up the print job – as part of the printing process, follow the respective printer instructions for use.

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.



Precaution: 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. 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 %).



Precaution: 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.

Preparation for post-curing

- Remove the support structure with the help of a cutting wheel or side cutters.
- Remove the white layer using a glass bead blasting material 50 µm (e. g. Perlablast® micro, REF 46092 / 54302) at a maximum blasting pressure of 1.5 bar.
- 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 components.

The post-curing of the object is done without use of a model, then allow to cool for 3–5 minutes or until the object feels cool.

VarseoSmile Temp 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://www.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-Otoflash	2 x 1,500 flashes	Turn object between the exposure cycles
BEGO Varseo L			
BEGO Varseo S			
BEGO Varseo XS	HiLite-Power*	2 x 90 seconds	
ASIGA MAX UV			



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



Precaution: If the post-curing process is interrupted by a malfunction, the printed object should not be used until it has been cured for one full cycle.

Refer to the operating instructions for the light-curing device to find out how the error can be resolved, and then repeat the post-curing process with the printed objects.

Supplementing / Repairing of printed objects

Defects (e. g. missing contact points, fractures, and so on) can be supplemented with the resin.

- Blast the areas to be supplemented with aluminum oxide – pressure 1.5 bar and particle size 110 µm (e. g. Korox® 110, BEGO).
- Put some liquid VarseoSmile Temp on the object.
- Put it under light for a short time (e. g. 5 flashes) in the BEGO Otoflash
- If more material has to be applied, put additional liquid VarseoSmile Temp on the last layer and then put it again under light for a short time (e. g. 5 flashes) in the BEGO Otoflash.
- Follow the instructions in the section “post-curing process” for final curing of the objects.



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.

8. Cleaning in the dental laboratory and dental practice

Fully cured crowns and bridges made from VarseoSmile Temp can be easily 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, Durr Dental Co.) is also possible.

Follow manufacturer’s instructions.

9. Notice for polishing and luting

- The temporary restoration can undergo high-gloss polishing with composite polishers commonly used in dental practice.
- The finished restoration can be attached using conventional temporary cements (e. g. Temp Bond NE*, Kerr Co.).
- If the subsequent temporary restoration is to be attached using methacrylate-based composite cement, the use of eugenol-free temporary cements is recommended.
- 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. 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.

11. Label symbols

 Manufacturer	 CE mark
 Date of manufacture	 Consult instructions for use
 Medical device	 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.