VarseoSmile Teeth

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Instructions for use

VarseoSmile Teeth

Resin for 3D printing of denture teeth for full or partial prosthesis.

1. Indications for Use

VarseoSmile Teeth is a light-curing, flowable resin based on methacrylic acid esters for the fabrication of denture teeth for full or partial dentures in cases of partial or complete edentulism.

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 Teeth should not be used for purposes other than denture teeth. Any deviation from these instructions for use can have negative effects on the chemical and physical quality of objects made from VarseoSmile Teeth.

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. In order to ensure optimum results, read the information contained in these instructions carefully.

The safety and precautions included in these instructions for use and the safety data sheet shall apply to the handling of both the liquid resin and printed objects that have not been post-cured (objects in the "green condition").

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

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 can also be 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.



DANGER

Information on hazards as per SDS

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



Contains:

sterification products of

4,4'-Isopropylidiphenol, ethoxylated and 2-met-

hylprop-2enoic acid, silanized dental glass,

methylbenzoylformate

diphenyl(2,4,6-tri-me-

thylbenzoyl) phosphine

Overall share of

Safety instructions as per SDS 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.

- . If on skin: Wash with plenty of water and
- . 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.
- If skin irritation occurs: Get medical advice/attention.
- · Take off contaminated clothing and wash it before reuse.
- · Wash contaminated clothing before reuse.

- Store in a well-ventilated place. Keep container tightly closed.
- · Store locked up.

Disposal

• Dispose of contents/container to a facility in inorganic Fillers (paraccordance with local and national regulaticle size 0.7 µm) totals

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

This product must be stored in the original sealed bottle, or 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.

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.

b. Nesting & preparation for printing

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

c. Printing

VarseoSmile Teeth 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

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 XS	405 nm	2.6.8.24 or higher	BEGO CAMCreator Print Version 1.14 or higher	BEG0
ASIGA MAX UV	385 nm	2018-09-03	ASIGA Composer	ASIGA



WARNING: When processing this material predictable results can only be expected 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

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 temperature for processing VarseoSmile Teeth resin is 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 and the compatibility overview on our website

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

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 Teeth. 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://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 ul-
- 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.
- Finish the objects completely. Finishing and contouring 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 Teeth 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

Light-curing Device	Exposure Cycles	Additional Information
BEGO-Otoflash	2 x 1,500 flashes	Turn object between the
HiLite-Power*	2 x 90 seconds	exposure cycles



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



uarantees a corresponding light intensity.

CAUTION: If there is an interruption or failure in the post-curing 202 device cycle, the printed object should be not 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.



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Supplementing of printed objects

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

- Blast the areas to be supplemented with $110~\mu m$ aluminum oxide (e.g. Korox® 110, BEGO) at 1.5~bar pressure.
- Remove sand and other particles with compressed air.
- Apply some liquid VarseoSmile Teeth to the object.
- Polymerize the object for a short time under light, e.g. five flashes in the BEGO Otoflash.
- $\bullet~$ If more material needs to be applied, apply VarseoSmile Teeth again to the last layer and polymerize it again with e.g. five flashes in the BEGO Otoflash
- Final polymerization of the objects is carried out as described in the section "Post-curing process"

Supplementing printed objects with veneering materials

The printed objects can also be supplemented with commercially available composite veneering materials (e.g. VITA VM LC*, Vita Zahnfabrik, and VITA VM LC flow*, Vita Zahnfabrik). Observe the instructions for use of the veneering material manufacturer.



CAUTION: The dental object may only be repaired or supplemented outside the patient's mouth and by a dental professional.

Tip: Optionally, the surface of the objects can be treated with light-curing glazing materials (e.g. Vita ENAMIC GLAZE*, Vita Zahnfabrik or GC OPTIGLAZE*, GC). Observe the instructions for use of the glaze material manufacturer.

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)

Optionally, the post-exposed (not polished) objects can be individualized with stains or veneering materials.

Individualization with stains

The individualization of the final polymerized objects can be carried out using commercially available composite stains (e.g. VITA ENAMIC STAIN*, Vita Zahnfabrik and GC OPTIGLAZE Color*, GC) and is the responsibility of the user. This may influence the shade result. The instructions for use of the stain manufacturer must be observed.

Individualization with veneering materials

The objects can also be customized with commercially available composite veneering materials (e.g. VITA VM LC*, VITA VM LC flow* Vita Zahnfabrik). The instructions for use of the veneering material manufacturer's instructions for use must be observed.

8. Cleaning in the dental laboratory and dental practice

Fully cured objects made from VarseoSmile Teeth may be steam cleaned (e.g. with Triton SLA) or cleaned in an immersion bath (e.g. ethanol 96 % or MD 520* impression disinfectant, Dürr Dental Co.).

Follow manufacturer's instructions

9. Connecting the printed teeth to a denture base material

The polymerized denture teeth can be connected to denture bases made of cold polymer or 3D-printed denture bases. To establish the connection with corresponding denture bases, please observe the respective valid instructions for use of the manufacturer of the denture base material.

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 corresponding 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

Consult instructions Manufacturer Date of manufacture Use-by date ⚠ Caution LOT Batch code Temperature limit REF. Catalogue number







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