

Surgical Guide Resin

Product Description : Prevest Surgical Guide Resin is a light-curing material for the 3D printing of dental surgical guides for use in DLP and LCD 3D printers as reactive to wavelength of light between 385nm and 405nm. The following instructions for use are for dental professionals who use Surgical Guide Resin as a material for single user dental surgical guides. This instruction for use also provides information about safety and environmental aspects.

Composition : Methacrylates, Photo-initiator, Inhibitor and Pigment.

Intended Purpose / Intended Use : Surgical Guide Resin is intended for the fabrication of 3D printed dental surgical guides. The product is classified as a class I medical device.

Indications for Use : It is a photopolymer resin used for 3D printing dental surgical guides to aid in dental implant placement procedure.

Indications for Hygiene : The dental model appliances produced with Surgical Guide Resin are mostly customized and intended for a single-patient. The cleaning of multi-use appliances between usages is must. The cleaning of the appliance with soap and warm water, or any over-the-counter, mild cleaning agents is also must.

Instructions for Use :

Processing : Make sure to work as clean as possible, dirty reservoirs or equipment can cause deformation and therefore failure of the printed objects! It is always advisable to use nitrile gloves when handling the Surgical Guide Resin up until the Finishing step.

Shake for 5 minutes before use : Shake the bottle for at least 5 minutes prior to the mixing process on the roller mixer. This is required to loosen the (possible) sediment from the bottom of the bottle.

Thoroughly mix before using : Mix the product for 2.0 hours before the first time use. Mix the product for 1.0 hour before each subsequent use. Mixing on a roller stirring device is necessary to disperse the resin and the pigment. Color deviation and print failures may occur when mixed insufficiently.

Fill printer resin tray : Make sure the temperature of the resin is between (20-25°C/68-77°F) and prevent exposure to (sun) light. Pour the resin in the resin tray of the 3D printer. Do not mix different batches of the same product.

Printer settings : Only use the calibrated and/or predetermined settings for your DLP or LCD 3D printer and Post Wash-Cure system as mentioned in Prevest website. The resin can only be used with a 385nm – 405nm UV light source.

Remove printed parts from platform : When the 3D printer has finished its program remove the building platform from the machine. Place the platform on plastic sheet. The printed parts can now be removed from the platform using a metal scraper.

Cleaning printed parts - Step 1 : Dip the printed parts in an ethanol/Isopropyl (>90%) and wash it using Post wash-cure system for at least 15 minutes. Remove the cleaned parts and again clean in ethanol/Isopropyl alcohol (>90%) using an ultrasonic bath for not more than 4-5 minutes as beyond this defect in printed parts may appear.

Finishing : After cleaning and drying, let the printed parts rest for at least 10 minutes to make sure that the printed parts are free of ethanol/isopropyl alcohol residue. Remove any support structures from the printed parts using plastic spatula.

Post-Curing : Place the printed parts in a Post wash-cure system for final polymerization. Post-curing is an UV-light treatment to ensure that printed parts obtain optimal polymer conversion. Through this the residual monomer is reduced to a minimum and the required mechanical properties are obtained. This procedure is necessary to achieve the desired material properties using the Post wash-cure system. To obtain stable cured parts use the prescribed curing time of 45-60 minutes and if possible, further gives cured parts an additional exposure of temperature min. 60°C / 140 °F for 15 minutes.

Warnings :

HAZARDOUS INGREDIENTS : diphenyl (2,4,6-trimethyl benzoyl) phosphine oxide; 7,7,9(or7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diylbismethacrylate

HAZARD STATEMENTS :

H317 May cause an allergic skin reaction.

Eu204 Contains isocyanates. May produce an allergic reaction.

H315 Causes skin irritation.

H335 May cause respiratory irritation.

H412 Harmful to aquatic life with long lasting effects.

H319 Causes serious eye irritation.

Precautions :

PRECAUTIONARY STATEMENTS :

P264: Wash skin thoroughly after handling

P270: Do not eat, drink or smoke when using this product.

P272: Contaminated work clothing should not be allowed out of the workplace.

P280: Wear protective gloves/protective clothing/eye protection/face protection.

P363 Wash contaminated clothing before reuse.

P273: Avoid release to the environment.

P301+312: IF SWALLOWED: Call a poison center or doctor/physician if you feel unwell.

P302+P352: IF ON SKIN: Wash with plenty of soap and water.

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310: Immediately call a poison center or doctor/physician.

P314: Get medical advice/attention if you feel unwell.

P330: Rinse mouth.

P333+P313: If skin irritation or rash occurs: Get medical advice/attention.

P362+364: Take off contaminated clothes and wash before use.

P501: Dispose of contents/container to an approved waste disposal plant.

Contraindications :

Surgical Guide Resin should not be used for any other purpose than as a 3D print resin for the manufacturing of dental surgical guides. Any deviation from this instruction for use may have adverse effect on the chemical and physical quality of Surgical Guide Resin. In case of an allergic reaction, please contact a medical physician.

Storage Conditions, Expiry Date and Transport : Store the resin in the original packaging or in a closed resin tray garage, preferably at room temperature in a dry and dark area.

Close the packaging after each use. The expiry date of the product is mentioned on the product label. In case of exceeding the expiry date, the product is no longer guaranteed in terms of treatment. Do not expose to UV-light. Standard transport conditions apply to this product. There are no restrictions for transport related to hazardous substances. Store at temperature between 5°C(41°F) to 30°C(86°F).

Shelf Life : 3 years from the date of manufacturing.

Presentation :

Surgical Guide Resin is available in clear transparent appearance.

Clear 1 Kg and Clear ½ kg.

Disposal conditions : The printed objects produced from Surgical Guide Resin materials are not considered an environmental hazard in their final, fully cured state. Surgical Guide Resin in its polymerized form are not environmentally harmful. Surgical Guide Resin in its liquid state should be treated as chemical waste. The unused and non-recyclable liquid materials should be disposed in accordance with federal, state, and local regulations.

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Symbol for "BATCH CODE" Symbol for "USE-BY DATE" Symbol for "NON STERILE" Symbol for "KEEP DRY" Symbol for "CAUTION" Symbol for "CONSULT INSTRUCTION FOR USE"

Symbol for "CATALOGUE NUMBER" Symbol for "AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY/EUROPEAN UNION" Symbol for "DO NOT USE IF PACKAGE IS DAMAGED" Symbol for "WARNING"

Symbol for "KEEP OUT OF THE REACH OF CHILDREN" Symbol for "MANUFACTURER" Symbol for "TEMPERATURE LIMIT" Symbol for "KEEP AWAY FROM SUNLIGHT" Symbol for "MEDICAL DEVICE" Symbol for "UNIQUE DEVICE IDENTIFIER"

The material has been developed solely for professional dental use. Application should be carried out strictly according to the instruction for use. Liability cannot be accepted for damages resulting from failure to observe the instructions of the stipulated area of applications. The user is responsible for testing the material for its suitability and use for any purpose not explicitly stated in this instruction sheet. Description and data constitute no warranty of attributes and are not binding. For feedback, complaints and reporting of unexpected events contact customer care.