

1. INTRODUCTION

The following instructions for use are for dental professionals who use Structomer® Permanent Crown & Bridges resin as a dental crown & bridges 3D printing material. Structomer® Permanent Crown & Bridges is intended for printing dental and orthodontic crowns. This instruction for use also provides information about safety and environmental aspects. Safety datasheet (MSDS) corresponding to the Structomer® Permanent Crown & Bridges material is available on <https://www.structo3d.com/> and with the local dealers.

2. INTENDED USE / INDICATION

Structomer® Structomer® Temporary Crown & Bridges is intended to be 3D printed into dental and orthodontic crowns used in dental applications. The crowns are individually manufactured by dental professionals. The crowns are designed to aid in dental applications.

3. HARDWARE REQUIREMENTS

Structomer® Permanent Crown & Bridges can be used in combination with all laser, DLP, and LCD-based 3D printers which support Structomer® material. Information about supported 3D printers can be obtained from Structo Pte. Ltd. (see Contact Information below).

Please follow the hardware instructions provided by the hardware manufacturer concerning the printing parameters and support structure recommendations for Structomer® Permanent Crown & Bridges.

4. CONTRAINDICATION

Any deviation from this instruction for use is not recommended. In case of an allergic reaction, please contact a medical physician. The printed models are for single use only and are not to be used in contact with any part of the human body.

5. SAFETY INSTRUCTIONS

Structomer® Permanent Crown & Bridges is produced and tested according to the most stringent quality standards. In order to ensure optimum processing, please read the information contained in this Instructions for Use (IFU) carefully. Improper use and failure to observe the information can have a detrimental effect on the device quality.

Nitrile gloves, goggles, and coat should be worn as means of personal protection during resin handling. For proper handling of the resin, refer to Structomer® Permanent Crown & Bridges safety datasheet (MSDS). However, tolerance and sensitivity to particular resin components may vary for each individual, possibly resulting in adverse effects. In such cases, the respective user should discontinue use of Structomer® Permanent Crown & Bridges.

6. MANUFACTURING PROCESS

Prepare

- Make sure that printer used is compatible with Structomer® Permanent Crown & Bridges
- Assign the suitable cloud profile.
- Define support structures if required.

Shake

- **Shake** bottle well before use (2 -5 mins).
- **Pour** Structomer® Permanent Crown & Bridges into printer reservoir upto **max-level** mark. Resin top- up is required after every print to maintain this level.
- To ensure resin homogeneity, gently mix sitting resin in the printer tank.

Build

- Before printing, manual mixing of the resin before each print is recommended.
- 3D **print** the desired crown and bridges

Remove

- Remove build platform off the 3D printer.
- Remove printed objects off the build platform immediately after print completion.
- Use a razor blade/knife to get under the borders of the printed part and gently ease off the entire part.

Clean

- Rinse the printed objects in an ultrasonic bath (Duration: 2 cycles x 2 minutes) to get rid of excess resin in 2 wash cycles.
- Fresh Isopropanol (at least 90% concentration) should be used as the cleaning agent for cycle 2

Dry

- Dry printed objects with compressed dry air to avoid residues of IPA on the object surface.
- In the absence of compressed air, the printed objects should be allowed sufficient time for natural drying.

UV Post-Cure

- Set **5 minutes at 60 degree C** as post curing duration.
- Remove printed objects out of the post- cure unit immediately after completion.

Note:

Repeat printing: For repeated printing cycles, top up resin in the printer tank up to the max. Mark and manually mix the remaining resin before each print.

UV post-curing: Full polymerization of printed object by UV post-curing is critical to achieve desired material properties and to

provide a functional end-product. The manufacturer's recommended processing time varies depending upon the type of PCU is used. 5 mins at 60 C in 405 nm multi directional LEDs [Curing Unit Spec. (405nm wavelength LED, 39Watt LED power and 91Watt Radiant power, Max temp. 80C)] and 15 minutes in a PCU with six 18W/71 lamps (Dulux L Blue); and six 18W/78 lamps (Dulux blue UV-A). Post-curing light sources need routine maintenance following the manufacturer's instructions.

7. GENERAL INFORMATION ON HANDLING

7.1. Delivery

Structomer® Permanent Crown & Bridges is supplied in 500 gm or 1 kg tightly sealed bottle. Check the following upon receipt of the materials:

- Integrity of the bottle & packaging.
- Bottle cap seal is intact and not broken.
- Received quantity against delivery order.
- Shipping documents and label designations.
- Material received not past its 'Use-by' date.

7.2. Storage

Structomer® Permanent Crown & Bridges must be stored in its original sealed bottle and kept away from sunlight to avoid undesired polymerization as the material is photosensitive. The expiry date printed on the product must be observed. Satisfactory processing cannot be guaranteed if materials that have exceeded their expiry date are used.

7.3. Cleaning

Fully cured dental models made from Structomer® Permanent Crown & Bridges can be easily cleaned of small particles using room temperature water and lint-free cloth.

7.4. Disposal

Structomer® Permanent Crown & Bridges in its liquid form is hazardous to the environment. It is recommended that resin waste (including resin residue in used isopropanol) be delivered to a chemical waste collection point and disposed of in accordance with all local and national regulations for chemical waste disposal. Residuals must be removed from packaging and when emptied, completely disposed of in accordance with the regulations for waste removal. Handle contaminated packages in the same way as the product itself. Incompletely emptied packaging must be disposed of in the form of disposal specified by the regional disposer.

8. HAZARDS AND PRECAUTIONS

8.1. Hazard Statements

- | | |
|------|---|
| H302 | Harmful if swallowed |
| H314 | Causes severe skin burns and eye damage |
| H315 | May cause skin irritation |
| H317 | May cause an allergic skin reaction |
| H319 | May cause serious eye irritation |
| H361 | Suspected of damaging fertility or the unborn child |

H411 Toxic to aquatic life with long lasting effects







8.2. Precautionary Statements (Prevention)

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|------|--|
| P202 | Do not handle until all safety precautions have been read and understood |
| P261 | Avoid breathing dust / fumes / gas / mist / vapours / spray |
| P264 | Wash skin thoroughly after handling |
| P272 | Contaminated work clothing should not be allowed out of the workplace |
| P273 | Avoid release to the environment |
| P280 | Wear protective gloves/protective clothing/eye protection |

8.3. Precautionary Statements (Response)

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|--------------------|--|
| P302 + P352 | IF ON SKIN (or hair): Wash with plenty of soap and water |
| P304 + P340 | IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing |
| P305 + P351 + P338 | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and continue rinsing |
| P312 | Call a POISON CENTER or doctor / physician if you feel unwell |
| P321 | Special treatment (see supplementary first aid instructions on this label) |
| P332 + P313 | If skin irritation occurs: Get medical advice/attention |
| P337 + P313 | If eye irritation persists: Get medical advice/attention |
| P362 | Take off contaminated clothing and wash before reuse |
| P391 | Collect spillage |

9. LABEL SYMBOLS

	Warning		Use-by date
	Consult Instructions for use		Manufacturer
	Batch code		Keep away from sunlight

10. CONTACT INFORMATION

10.1. Distribution & Manufacturer

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