

1. INTRODUCTION

The following instructions for use are for dental professionals who use Structomer® Guide as a dental surgical guide 3D printing material. Structomer® Guide is intended exclusively for professional dental work. This instruction for use also provides information about safety and environmental aspects. Safety datasheet (MSDS) corresponding to the Structomer® Guide material is available on <https://www.structo3d.com/> and with the local dealers.

2. INTENDED USE / INDICATION

Structomer® Guide is intended to be 3D printed into surgical guides used in dental applications. The surgical guides are individually manufactured by dental professionals. The surgical guide is designed to aid in dental surgery.

3. HARDWARE REQUIREMENTS

Structomer® Guide can be used in combination with all laser, DLP and LCD based 3D printers which support Structomer® Guide materials. 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® Guide.

4. CONTRAINDICATION

Any deviation from this instruction for use is not recommended. In case of an allergic reaction, please contact a medical physician. 3D printed medical devices produced using Structomer® Guide should not be re-used across patients or for the same patient.

5. SAFETY INSTRUCTIONS

Structomer® Guide 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® Guide safety datasheet (MSDS).

6. MANUFACTURING PROCESS

Prepare

- Make sure that printer used is compatible with Structomer® Guide.
- Define the printing parameters desired.
- Define support structures required.

Shake

- Shake bottle well before use.
- Pour Structomer® Guide into printer reservoir.

Build

- 3D print the desired surgical guides.

Remove

- Remove build platform off the 3D printer.
- Remove printed objects off the build platform.

Clean

- Rinse the printed objects, utilizing ultrasonic bath (duration: 5 minutes) to get rid of any excess materials.
- Isopropanol with at least 90% concentration should be used as the cleaning agent.

Remove

- Remove support structures.

Clean

- Rinse the printed objects again, utilizing ultrasonic bath (duration: 5 - 10 minutes) to clean the printed objects fully.
- Fresh Isopropanol with at least 90% concentration must be used as the cleaning agent.

Dry

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

Post-Cure

- Post curing duration vary depending upon the type of Post curing unit used. 1 min in Metal halide lamp PCU, 5 mins at 60 °C in 405nm UV LED light PCU & 20 mins in a PCU combination of UV-A(315-400nm) and UV-Blue (400-550 nm) bulb.

Note: Full polymerization of printed object by post curing is critical to achieve desired material properties and to provide a biocompatible end-product. The manufacturer's recommended processing time is 20 minutes. The value was measured using a device with the following output; six 18W/71 lamps (Dulux L Blue); and six 18W/78 lamps (Dulux blue UV-A).

Note: Post-curing light sources need routine maintenance following manufacturer's instruction.

7. GENERAL INFORMATION ON HANDLING

7.1. Delivery

Structomer® Guide is supplied in 1kg 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
- Materials received not past its 'Use-by' date.

7.2. Storage

Structomer® Guide must be stored in its original sealed bottle at room temperature (approx. 25 °C) in a dark and dry area. The minimum shelf life date printed on the product must be observed. Perfect processing cannot be guaranteed if materials which have exceeded their minimum shelf life date are used.

7.3. Cleaning

Fully cured surgical guides made from Structomer® Guide can be easily cleaned with non-chemical products and disinfected with ethanol solution.

7.4. Disposal

Structomer® Guide in its polymerized form is not harmful to the environment. Residual waste material in its liquid state (unused Structomer® Guide or used Isopropanol) should be delivered to a collection point for chemical waste material.

8. HAZARDS AND PRECAUTIONS

8.1. Hazard Statements

H317	May cause an allergic skin reaction
H413	May cause long lasting harmful effects to the aquatic life
H315	May cause skin irritation
H319	May cause serious eye irritation
H335	May cause respiratory irritation

8.2. Precautionary Statements (Prevention)

P280	Wear protective gloves.
P261	Avoid breathing dust / fumes / gas / mist / vapors / spray.
P273	Avoid release to the environment.
P272	Contaminated work clothing should not be allowed out of the workplace.
P264	Wash skin thoroughly after handling.

8.3. Precautionary Statements (Response)

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.

9. LABEL SYMBOLS



Warning



CE Mark



Consult Instructions for use



Use-by date



Batch code



EU Authorized representative



Keep away from sunlight



Manufacturer

10. CONTACT INFORMATION

10.1. Distribution & Manufacturer

Sales & Distribution:

Structo Pte.Ltd.
 114 Lavender Street,
 #07-53 CT Hub 2,
 Singapore 338729.

Tel: +65 6514 7332

Email: sales@structo3d.com

Web: www.structo3d.com

Manufacturer:

Structo Pte. Ltd.
 155 Kallang Way #05-09/10,
 Singapore 349244.

Tel: +65 6920 2526

Email: materials@structo3d.com

Web: www.structo3d.com

10.2. EU Authorized Representative

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 Altenhofstrasse 80,
 66386 St.Ingbert, Germany.

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