

1. INTRODUCTION

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

2. INTENDED USE / INDICATION

Structomer[®] Tray is intended to be 3D printed into customized impression trays for the use in dental applications. The impression trays are individually manufactured by dental professionals.

3. HARDWARE REQUIREMENTS

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

4. CONTRAINDICATION

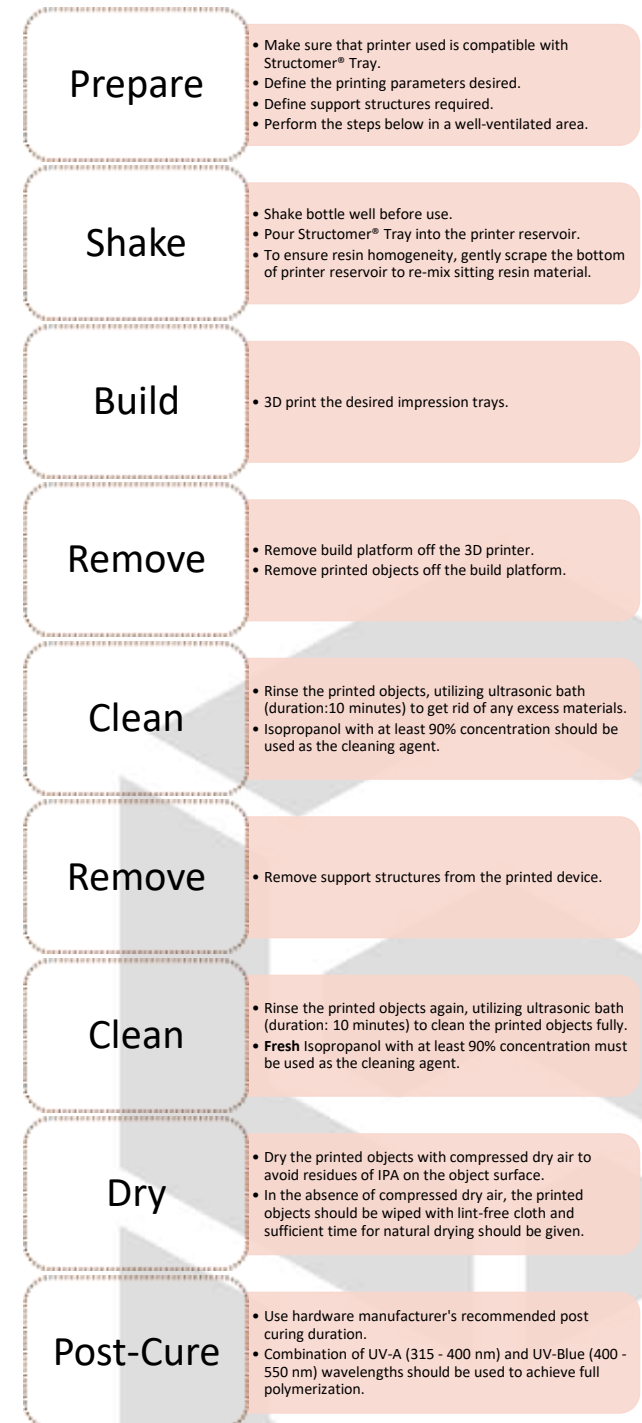
Any deviation from this instruction for use is not recommended. In case of an allergic reaction, please contact a medical physician. 3D printed medical devices manufactured using Structomer[®] Tray should not be re-used across patients or for the same patient.

5. SAFETY INSTRUCTIONS

Structomer[®] Tray is produced and tested according to the most stringent quality standards. 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 device quality and adverse effects on health.

Nitrile gloves, goggles and lab coat should be worn as means of personal protection during resin handling. For proper handling of the resin, refer to Structomer[®] Tray material 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[®] Tray.

6. MANUFACTURING PROCESS



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[®] Tray is supplied in 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
- Materials received not past its 'Use-by' date.

7.2. Storage

Structomer[®] Tray must be stored in its original sealed bottle and kept away from sunlight to avoid undesired polymerization as the material is photo-sensitive. The expiry date printed on the product must be observed. Satisfactory processing cannot be guaranteed if materials which have exceeded their expiry date are used.

7.3. Disinfection

Fully cured impression trays made from Structomer[®] Tray can be easily disinfected with ethanol prior to dental impression acquiring.

7.4. Disposal

Structomer[®] Tray in its polymerized form is not harmful to the environment. Residual waste material in its liquid state (unused Structomer[®] Tray resin) should be delivered to a collection point for chemical waste. 3D printed dental trays are for single use and should be disposed of with the general waste immediately after.

8. HAZARDS AND PRECAUTIONS

8.1. Hazard Statements

H302	Harmful if swallowed.
H315	May cause skin irritation.
H317	May cause an allergic skin reaction.
H319	May cause serious eye irritation.
H335	May cause respiratory irritation.
H413	May cause long lasting harmful effects to the aquatic life.

8.2. Precautionary Statements (Prevention)

P261	Avoid breathing dust / fumes / gas / mist / vapors / 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.

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

11. 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

12. EU Authorized Representative

MT Promedt Consulting GmbH
 Altenhofstrasse 80, 66386 St.Ingbert, Germany.
 Tel: +49 6894 581020

Email: info@mt-procons.com

Web: www.mt-procons.com