1. INTRODUCTION

The following instructions for use are for Healthcare professionals who use Structomer® Clear resin as a Anatomy Model 3D printing material. Structomer® Clear is intended for printing Anatomical Models such as Flexible forearm bone, Humerus bone and heart etc.This instruction for use also provides information about safety and environmental aspects. Safety datasheet (MSDS) corresponding to the Structomer® Clear material is available on https://www.structo3d.com/ and with the local dealers.

2. INTENDED USE / INDICATION

Structomer® Clear resin is designed for 3D printing anatomical models used in healthcare applications, such as pre-surgical planning and demonstration. The Clear Models are individually manufactured by healthcare professionals. Clear Models are designed to aid in healthcare applications.

3. HARDWARE REQUIREMENTS

Structomer® Clear 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® Clears.

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® Clear 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 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® Clear 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 ofStructomer® Clear resin.

Prepare	• Make sure that printer used is compatible with Structomer® Clear resin • Assign the suitable cloud profile. • Define support structures if required.
Shake	• **Shake** bottle well before use (2 -5 mins). • **Pour** Structomer® Clear resin 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 dental models (upto 9 horizontal solid arches per print).
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 [IPA wash or Solventless wash (Spin)]	• 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. • Spin the printed objects in a Spinner (Structo G-01)
Dry for IPA wash	• 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	• Post curing duration vary depending upon the type of Post curing unit used. 1 min in Metal halide lamp PCU, 5 mins at 60 ^{0}C in 405nm UV LED light PCU & 15 mins in a PCU combination of UV-A(315-400nm) and UV-Blue (400-550 nm) bulb. • Remove printed objects out of the post-cure unit immediately after completion.

6. MANUFACTURING PROCESS

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. 1 min in Metal Halide lamp type PCU , 5 mins at 60 C in 405 nm multi directional LEDs 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 manufacturer's instruction.

7. GENERAL INFORMATION ON HANDLING

7.1. Delivery

Structomer® Clear is supplied in 1 kg or 5 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® Clear 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. Cleaning

Fully cured dental crowns made from Structomer® Clear can be easily cleaned of small particles using room temperature water and lint free cloth.

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)

P202	Do not handle until all safety precautions have been read and understood.
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/protective clothing/eye protection.

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.

7.4. Disposal

Structomer® Clear in its liquid form is hazardous to the environment. It is recommended that resin waste (including resin residue in used isopropanol) be deliveredto a chemical waste collection point and disposed in accordance with all local and national regulations for chemical waste disposal. Residuals must be removedfrom packaging and when emptied, completely disposedoff 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.

P312	Call a POISION CENTER or doctor / physician if you feel unwell.
P321	Special treatment (see supplementary first aid instructions on this label).
P312	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

Sales & Distribution:

Structo Pte. Ltd.
60 MacPherson Road
Block 1 #04-08
Singapore 348615

Tel: +65 6514 7332
Email: sales@structo3d.com
Web: www.structo3d.com

Manufacturer:

Structo Pte. Ltd.
3 Kallang Sector
#03-05/06
Singapore 349278

Tel: +65 6514 7332
Email: materials@structo3d.com
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