Structomer Hard Splint

Instructions for Use (IFU)

3D Printing Resin for Hard Splint

For Professional Dental Use Only

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1. Product Description

Structomer Hard Splint is a Class II, biocompatible 3D printing resin formulated for the fabrication of full maxillary arch custom bite splints and corrective oral appliances. It is designed for use with CAD/CAM systems and validated 3D printing and post-curing devices.

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2. Composition

Structomer Hard Splint resin consists of:

- Dimethacrylate-based resin
- Photoinitiator
- Monomer (Diluents)
- Additives

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3. Intended Users

This product is intended for use exclusively by trained dental professionals, including licensed dentists and dental laboratory technicians.
Sales are restricted to:

- Licensed dental professionals
- Dental supply distributors
- Educational institutions
- Government dental facilities

Note: This product is labelled for use by licensed practitioners only, unless permitted by local or state law.

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4. Indications for Use

Structomer Hard Splint resin is indicated for:

- Custom full-arch bite splints
- Mouthguards for bruxism (teeth grinding)
- Anti-snoring oral appliances

This resin is to be used in conjunction with a complete CAD/CAM system, which includes:

- Oral impression or intraoral scan
- Digital design file
- 3D additive manufacturing printer (stereolithography)
- Post-curing equipment

Use only with the validated printers and post-curing devices listed in this guide, following all manufacturer recommendations.

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5. Contraindications

- Do not design bite splints with thicknesses below **0.75 mm**, as this may result in breakage or deformation during removal from the patient's mouth.

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6. Design Orientation & Support Recommendations

6.1 Orient bite splints with the adaptive (occlusal) surface angled **downward at 45°**.
6.2 Place support structures around the **perimeter of the ridge**. Avoid placing supports on adaptive or gingival contact areas.
6.3 **Minimum support diameter:** 0.3 mm at contact point
6.4 **Minimum support height:** 2 mm (to ensure easy removal from build plate)

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7. Mixing Instructions

Thorough mixing is essential due to the different weights of resin components.

- **7.1 Resin in Vat:** Stir gently with a silicone spatula if idle for more than 4 hours.
- **7.2 From Bottle:** Shake or stir with a plastic spatula for at least 1 minute, or use a bottle roller for 10 minutes.
- **7.3 Long-term Storage:** If the resin has been stored for over 1 month, roll the bottle for **1 hour** before use.

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8. Post-Processing Instructions

8.1 Remove build plate after printing.
8.2 Clean parts in **98% IPA**:

- 1st bath (ultrasonic): 2 minutes
- 2nd bath with fresh IPA: 2 minutes
  Do not exceed 4 minutes total IPA exposure to avoid weakening the material.
  8.3 Use compressed air to dry parts and remove uncured resin.
  8.4 Repeat cleaning until a **matte, shine-free** finish is achieved.

8.5 Post-cure using a validated device according to recommended time and temperature (see Section 10).

Post-curing is required for FDA compliance.

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9. Validated 3D Printers

Use only the following validated printers (wavelength 405nm):

- Structo Dentaform

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10. Validated Post-Curing Devices

- **Formlabs Form Cure, Fisrt Gen.**: 5mins at 60 ^{0}C
  - Light Source: 13 multi-directional LEDs
  - LED Power: 39 W
  - LED Radiant: 9.1 W
  - LED Wavelength: 405 nm

- Structo Postcuring Units: 15mins

  Light source: Six 18W/71 lamps (Dulux L Blue) and six 18W/78 lamps (Dulux blue UV-A)

No vacuum or inert gas environment is required.

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11. Chairside Adjustments & Impressions

11.1 Adjustments:
Use standard dental carbide burs to modify the bite splint. Smooth sharp areas using polishing wheels.

11.2 Impression Taking:
Follow the impression material manufacturer's instructions and ensure full set before removal.

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12. Storage and Handling Conditions

12.1 Light Sensitivity:
Keep resin away from direct sunlight and ambient light. Cover resin vats when not in use.

12.2 Temperature:

- **Storage:** 65°F – 85°F (18°C – 29°C)
- **Printing:** Ideally at 30°C
  If stored in cold environments, warm the sealed resin bottle in a water bath before use.

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13. Long-Term Storage & End-of-Day Procedures

- Return unused resin to the original bottle using a **fine mesh filter**.
- Store in **original packaging** at room temperature in a **cool, dry, dark place**.
- Keep container tightly closed when not in use.
- **Shelf Life:**
  - In bottle: Up to **12 months**
  - In printer: Up to **1 week** with hood closed
- Do **not expose to UV light**.
- Standard transport conditions apply; **no special hazardous material protocols** required.

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14. Disposal Guidelines

Dispose of resin in accordance with **federal, state, and local** regulations.

- Refer to Structo soft splint MSDS for hazardous waste classification.
- **Cure liquid resin** before disposal: pour into a clear container and expose to sunlight until hardened.
- Cured resin may be discarded in regular trash.

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15. Legal Notice

Structo assumes no liability for misuse of this product, including:

- Use of non-validated equipment
- Deviation from the instructions provided
  Such actions may affect the performance, safety, or effectiveness of the final restoration.

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16. Packaging Information

- **Available Variant:**
  - **Color:** Clear
  - **Unit Size:** 1kg & 5kg bottle
