

SPLINT BIOCOMPATIBLE RESIN

1. Product Overview

SPLINT™ Resin is a high-strength, easy-to-print resin developed for producing night guards, occlusal splints, and bite plates using DLP and MSLA 3D printers. It offers excellent fracture resistance, smooth surface finish, and stable intraoral fit over time. Designed with a low-odour formulation and reliable curing profile, SPLINT™ delivers high-quality results while simplifying the digital workflow for dental professionals and labs.

2. Key Features & Benefits

- ✓ High strength and dimensional stability
- ✓ Smooth surface finish straight from the printer
- ✓ Low odour formulation for easier handling
- ✓ Clear material for aesthetic appliances
- ✓ Excellent long-term wear resistance
- ✓ Compatible with DLP & MSLA 3D printers

3. Applications

- Occlusal splints
- Night guards
- Bite plates
- Bruxism appliances
- TMJ treatment devices

4. Physical Properties

| Property | SPLINT™ Flex | Rigid | Test Method |
|-------------------------|--------------|--------|-------------|
| Appearance | Clear | Clear | Visual |
| Odour | 1. Low | 1. Low | VDA 270 |
| Tensile Strength (MPa) | 46-52 | 61-72 | ASTM D790 |
| Flexural Strength (MPa) | 45 | 48 | ASTM E1356 |
| Elongation at Break (%) | 105 | 20 | ASTM D638 |
| Viscosity @ 25°C cP | 600 | 700 | ASTM D2196 |
| Density g/cm³ | 1.1 | 1.1 | ASTM D792 |
| Hardness (Shore D) | 85 | 92 | ASTM D2240 |
| Flexural Modulus (MPa) | ~1,000–1,400 | >2,500 | ASTM D790 |

5. Printer Compatibility

- Compatible with MSLA & DLP 3D Printers
- Asiga, SprintRay, Phrozen, Anycubic, Elegoo, and more
- Curing wavelength: 365–405nm UV

10. Disclaimer

The information provided in this Technical Data Sheet is based on laboratory testing and intended as a general guideline. Actual results may vary depending on printing conditions, curing methods, and environmental factors. Monocure3D assumes no liability for improper use of this product.

6. Printing & Post-Processing Guidelines

Printing Parameters

Layer Thickness: 50–150µm
Base Layer Exposure: 30 seconds
Normal Layer Exposure: 3-5 seconds
Lift Speed: 70 mm/s
Lift Height: 10-15 mm



(Refer to printer settings database)

Post-Processing Steps

1. Pre-wash in ResinAway® & brush to remove excess resin
2. Submerge in ResinAway® in Ultrasonic for 5-10 minutes.
2. Dry the Model – Allow to air-dry or use compressed air.
3. Post-Cure – UV cure for 30-60 minutes.
4. OTTOFLASH G171: 2,000 flashes (recommended)
5. Final Finishing – Rinse with Fresh Water.

7. Health & Safety Information

- While this resin is not listed on the ARTG, the raw materials used in SPLINT™ are supplied by a manufacturer whose base oligomers are registered under the European REACH system as biocompatible. These materials are commonly used in certified medical and dental applications globally.
- Use in a well-ventilated area and avoid direct skin or eye contact with uncured resin. If contact occurs, wash thoroughly with soap and water. Refer to the Safety Data Sheet (SDS) for full handling instructions.

- More info: www.monocure3d.com.au

8. Storage & Handling

- **Storage Temperature:** 10–30°C (Avoid direct sunlight)
- **Shelf Life:** 24 months
- **Handling:** Use recommend red PPE eg. **gloves & safety goggles** when handling liquid resin
- **Disposal:** Follow **local hazardous waste disposal regulations**.

9. Ordering Information

- **Available Sizes:** 500g, 1kg & 5kg UV-safe bottles
- **Where to Buy:** Available through **Monocure3D resellers**
- For technical support or bulk orders, contact:

support@monocure3d.com.au | www.monocure3d.com.au

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Q1. Why doesn't Monocure3D's SPLINT™ Resin need to be listed on the ARTG?

Monocure3D's SPLINT™ resin is **not required** to be included in the Australian Register of Therapeutic Goods (ARTG), following updated guidance from the Therapeutic Goods Administration (TGA) issued in August 2024. This is because the resin is classified as a starting material, not a finished medical device.

In written advice received from the ARTG (August 2024):

“Starting materials or components used in the manufacture of a medical device (i.e. resins used in 3D printers) generally do not meet the definition of a medical device, and do not need to be included in the Australia Register of Therapeutic Goods (ARTG) before they are supplied to a manufacturer.”

— Devices Emerging Technology Section, TGA

This means that resins like SPLINT™, which are used to manufacture dental appliances such as night guards and occlusal splints, **do not require ARTG listing themselves**.

Q2. When is a ARTG listing is required for a 3D Printing Resin?

The only exception is if a material is considered a specified article under the Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020. These are materials intended for:

- **Direct restoration of teeth**
- **Indirect restoration of teeth**
- **Taking dental impressions**
- **Manufacturing non-implantable dental appliances**

“In this case it does not appear this material is intended by its manufacturer for such application.”

— Brian Chamberlain, Medical Device Information Unit, ARTG



Because Monocure3D's SPLINT™ resin is not intended for restorations or impressions, and is only used to produce splints or night guards via 3D printing, it is not classified as a specified article and therefore **does not require ARTG inclusion**.

Q3. Can I use SPLINT™ resin in my dental practice or lab without ARTG concerns?

Yes, you can. SPLINT™ resin is classified as a starting material, not a finished medical device. As confirmed by the TGA, this means:

- It does **not require ARTG listing**.
- It is **not regulated as a specified article**, as it is not intended for restorations or impressions.
- It is suitable for **manufacturing occlusal splints and night guards** within a dental setting.
- If you're producing devices under the instruction of a health practitioner, you may also be covered by the Schedule 4 exemption, allowing manufacture and use within a clinical environment.
- Always ensure that your final printed devices are processed correctly and used in line with the appropriate clinical standards.

Disclaimer

This fact sheet is provided as general information only and is based on guidance received from the Therapeutic Goods Administration (TGA) as of August 2024. It does not constitute legal or regulatory advice. While Monocure3D has taken care to ensure the accuracy of this information, it is the responsibility of each practitioner or laboratory to ensure compliance with current Australian regulations and to seek independent legal or regulatory advice where necessary. Monocure3D accepts no liability for the use or misuse of this information. Regulatory requirements may change, and it is recommended you refer to the TGA or a qualified advisor for the most up-to-date guidance.