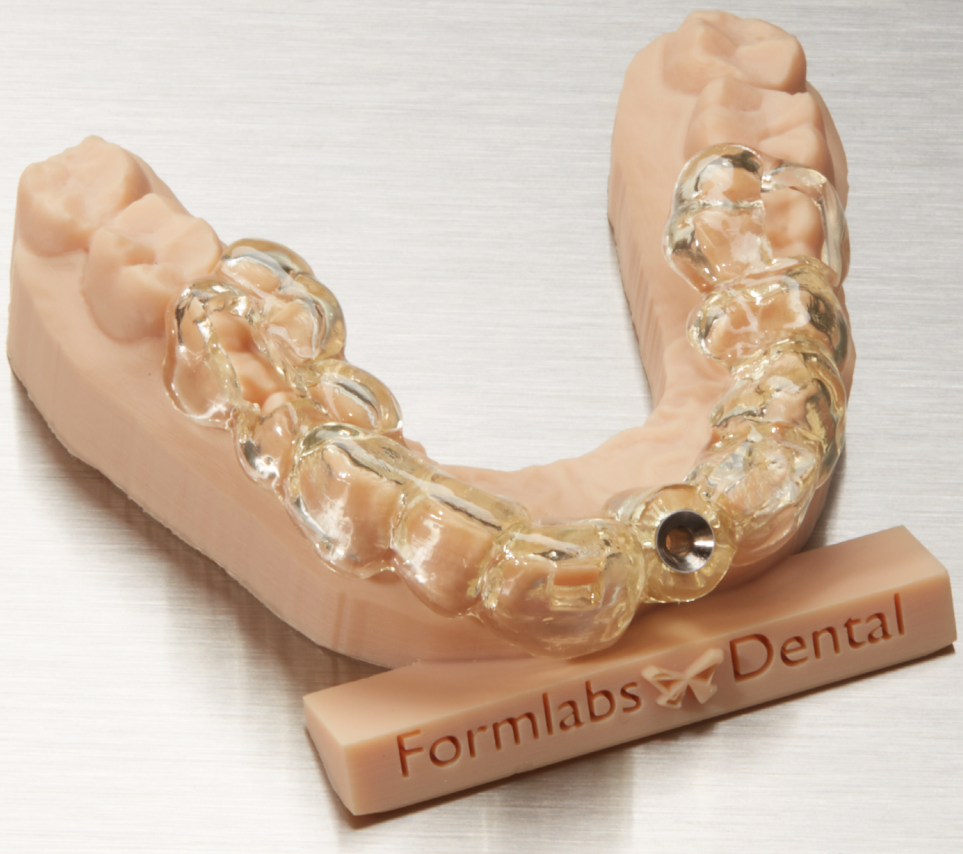
MATERIAL DATA SHEET

# Surgical Guide

## Biocompatible Photopolymer Resin for Form 2 and Form 3B

Surgical Guide Resin is a CE certified, biocompatible material that meets Class I requirements. This clear resin is designed to print at 100 micron and 50 micron layer line resolutions on Form printers to produce dimensionally accurate implant guides and templates. After being post-cured, this material can be chemically disinfected or steam sterilized in an autoclave.

- Surgical Guides
- Drilling Templates
- Pilot Drill Guides
- Device Sizing Templates




V1 **FLSGAM01**

formlabs

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# Material Properties Data

| | METRIC | IMPERIAL | METHOD |
|---|---|---|---|
| | Post-Cured [1,2] | Post-Cured [1,2] | |
| **Tensile Properties** | | | |
| Ultimate Tensile Strength | 73 MPa | 11 ksi | ASTM D638-10 (Type IV) |
| Young's Modulus | 2.9 GPa | 420 ksi | ASTM D638-10 (Type IV) |
| Elongation | 12.3% | 12.3% | ASTM D638-10 (Type IV) |
| **Flexural Properties** | | | |
| Flexural Strength | 103 MPa | 15 ksi | ASTM D790-15 (Method B) |
| Flexural Modulus | 2.5 GPa | 363 ksi | ASTM D790-15 (Method B |
| **Hardness Properties** | | | |
| Hardness Shore D | 67 D | 67 D | ASTM D2240-15 (Type D) |

| **Disinfection Compatibility** | |
|---|---|
| Chemical Disinfection | 70% Isopropyl Alcohol for 5 minutes |
| Steam Sterilization | Autoclave at 134 °C for 20 minutes<br>Autoclave at 121 °C for 30 minutes |

Surgical Guide Resin is a Class I Medical Device as defined in Article I of the Medical Device Directive (93/42/EEC) in the EU and in Section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act.

Surgical Guide Resin has been evaluated in accordance with ISO 10993-1:2018, Biological evaluation of medical devices - *Part 1: Evaluation and testing within a risk management process, and ISO 7405:2009/(R)2015, Dentistry - Evaluation of biocompatibility of medical devices used in dentistry*, **and passed the requirements for the following biocompatibility risks:**

| ISO Standard | Description [3] |
|---|---|
| EN ISO 10993-5:2009 | Not Cytotoxic |
| ISO 10993-10:2010/(R)2014 | Non Irritation |
| ISO 10993-10:2010/(R)2014 | Not a sensitizer |

**The product was developed and is in compliance with the following ISO Standards:**

| ISO Standard | Description |
|---|---|
| EN ISO 13485:2016 | Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes |
| EN ISO 14971:2012 | Medical Devices – Application of Risk Management to Medical Devices |

**NOTES:**

[1] Material properties may vary based on part geometry, print orientation, print settings, temperature, and disinfection or sterilization methods used.

[2] Data for post-cured samples were measured on Type IV tensile bars printed on a Form 2 printer with 100 µm Surgical Guide Resin settings, washed in a Form Wash for 20 minutes in 99 % Isopropyl Alcohol, and post-cured at 60 °C for 30 minutes in a Form Cure.

[3] Surgical Guide Resin was tested at NAMSA World Headquarters, OH, USA.