formlabs | dental

DENTAL RESIN

Surgical Guide Resin

A premium-quality material for printing surgical implant guides

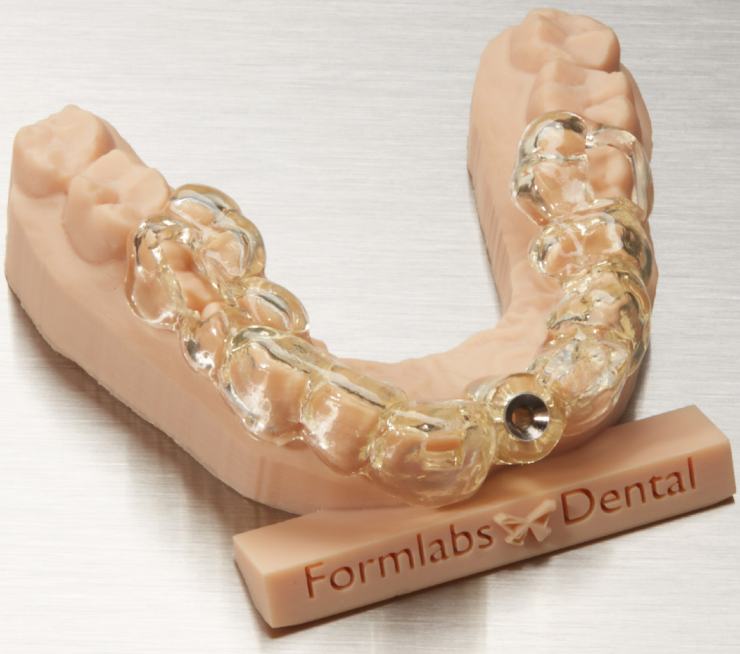
Surgical Guide Resin is designed to print at 100 micron and 50 micron layer line resolutions on Formlabs SLA printers to produce dimensionally accurate dental implant guides and templates.

Surgical guides

Pilot drill guides

Device sizing templates

Drilling templates



V1 **FLSGAM01**

*** May not be available in all regions**

Prepared 11/04/2019

Rev. 02 21/07/2021

Material Properties	Post-Cured [1, 2]	Method
Elongation at Break	12%	ASTM D638
Flexural Strength	> 102 MPa	ASTM D790
Flexural Modulus	> 2400 MPa	ASTM D790

Sterilization Compatibility	
E-beam	35 kGy E-beam radiation
Ethylene Oxide	100% Ethylene oxide at 55 °C for 180 minutes
Gamma	29.4 - 31.2 kGy gamma radiation
Steam Sterilization	Autoclave at 134 °C for 20 minutes Autoclave at 121 °C for 30 minutes

For more details on sterilization compatibilities, visit formlabs.com

Disinfection Compatibility	
Chemical Disinfection	70% Isopropyl Alcohol for 5 minutes

Surgical Guide Resin is a Class I Medical Device as defined in Article 2 of the Medical Device Regulation 2017/74 (MDR) 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, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, and ISO 7405, 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	Not cytotoxic
EN ISO 10993-10	Not an irritant
EN ISO 10993-10	Not a sensitizer

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

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

[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.