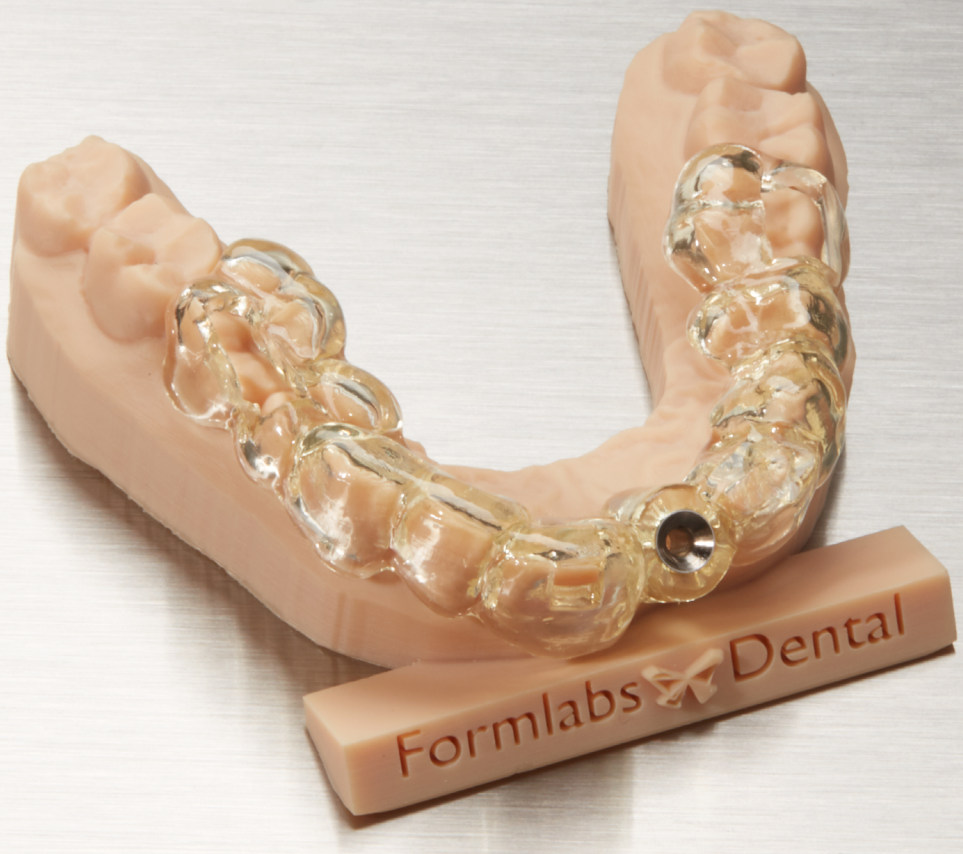
MATERIAL DATA SHEET

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 Formlabs SLA 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**

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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 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.