



Biocompatibility and Sterility Information

All Surgical Guides are printed from either Formlabs BioMed Clear Resin or Formlabs BioMed Amber Resin. All bone models are printed from either Formlabs Standard White V4 Resin or Formlabs Standard White V5 Resin. For more information on these resins, please visit the Formlabs materials website: <https://formlabs.com/materials/>

Surgical Guides

All surgical guides printed from BioMed Amber or BioMed Clear are supplied non-sterile. They require either autoclave or gas sterilization before use. The following sterilization guidelines are recommended:

- Ethylene Oxide: 100% Ethylene oxide at 55°C for 180 minutes
- Steam Sterilization: Autoclave at 134°C for 20 minutes or at 121°C for 30 minutes

Once sterilized, surgical guides are rated Class 1 biocompatible by Formlabs. BioMed Amber Resin and BioMed Clear Resin have been evaluated in accordance with ISO 10993-1:2018 and passed requirements to ensure they are not cytotoxic, not an irritant, not a sensitizer, non-pyrogenic, and with no evidence of acute systemic toxicity.

Bone Models

All bone models printed from Standard White V4 Resin and Standard White V5 Resin are non-biocompatible.