

DD GUIDE Dental Surgical Guide

3D printing resin for dental surgical guides













Version 1.3 2018/05/24

The following instruction is intended exclusively for dental professionals, such as dentists, oral maxillofacial surgeons and dental technicians to print dental surgical guides using DD GUIDE Dental Surgical Guide resin. For safety datasheets, please visit www.enlightenmaterials.com for more information.

Introduction

DD GUIDE Dental Surgical Guide is a monomer-based acrylic resin for the printing of dental surgical guides with high flexural strength, low shrinkage and excellent cytocompatibility using high resolution 3D printers. It is a Class I material and certified by TFDA. It is developed by ENLIGHTEN MATERIALS Co., Ltd.

Explanation of symbols on labelling

	CE mark		Consult instructions for use
	Batch code		Nonsterile
	Manufacturer and date of manufacture		Keep away from direct sunlight or room light
	Caution: may causes skin irritation, allergic skin reaction, serious eye irritation, respiratory irritation or long lasting harmful effects to aquatic life		Temperature limitation from 18°C to 35°C
	Use by date		Authorized representative in the European community

Hazard and precaution

H315 Causes skin irritation.

H317 May cause an allergic skin reaction

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H413 May cause long lasting harmful effects to aquatic life

Intended use

Implant Surgical Guides

Suitable 3D printers

DD GUIDE Dental Surgical Guide can be used for DLP and SLA 3D printers with 405nm light source.

Contraindication

DD GUIDE Dental Surgical Guide should not be used for any other applications other than dental surgical guides.

Storage and transportation

DD GUIDE Dental Surgical Guide should be stored and transported in the original package at room temperature in a dark area, preferably not exceeding 25°C. The expiry date of the resin is shown on the label. Do NOT use the resin if the expiry date is exceeded. After the printing the resin, the resin left in the resin tank of a 3D printer should NOT be mixed and stored with the unused resin. It should be stored in another light-proof container.

Procedures for printing and post-processing

Please read the safety data carefully before using DD GUIDE Dental Surgical Guide. Shake DD GUIDE Dental Surgical Guide well in the original packaging for 1 minute before using it. It is recommended to wear nitrile gloves when using DD GUIDE Dental Guide until post-curing procedure is completed.

1. Printing

Pour DD GUIDE dental surgical guide resin into the resin tank of a 3D printer, and import the surgical guide model into the 3D printer for printing.

2. Washing

Remove the printed surgical guide from the build platform and soak in IPA (isopropanol) or 95% ethanol to remove the extra resin. Use an ultrasonic cleaner if necessary. Please be aware that IPA and ethanol must NOT be placed directly in the tank of the ultrasonic cleaner.

3. Drying

Ensure the surgical guide clean. Do not remain liquid resin or ethanol.

4. Post-Curing

For post-curing, the curing energy and curing time depends on the post-curing unit. For example, a good surface hardness and biocompatibility can be achieved by 15 minutes of post-curing using Formlabs FormCure

curing box at 405nm at 60°C.

Sterilization

Sterilization of the printed surgical guide using 70% ethanol is recommended. Do NOT use autoclave for sterilization.

Material Properties

Property	Value
Flexural Strength	>1900 MPa
Flexural Modulus	>90 MPa
Hardness	>80 Shore D
Viscosity	0.72 Pa·s

Biocompatibility testing (According to EN-ISO 10993-5:2009)

Sample	Received Date	Result 1: Morphology	Result 2: MTT assay	Average	Cytotoxicity
DD guide	2018.01.26	0	0	0	None

Cytotoxicity: 0 = None, 0~1 = Slight, 1~2 = Mild, 2~3 = Moderate, 3~4 = Severe.

Extraction medium condition

Sample	Received Date	Surface Area (cm ²)	Volume of Extraction Medium (ml)	Extraction Temp (°C)
DD GUIDE dental surgical guide	2018.01.26	6	2	37

Qualitative morphological grading

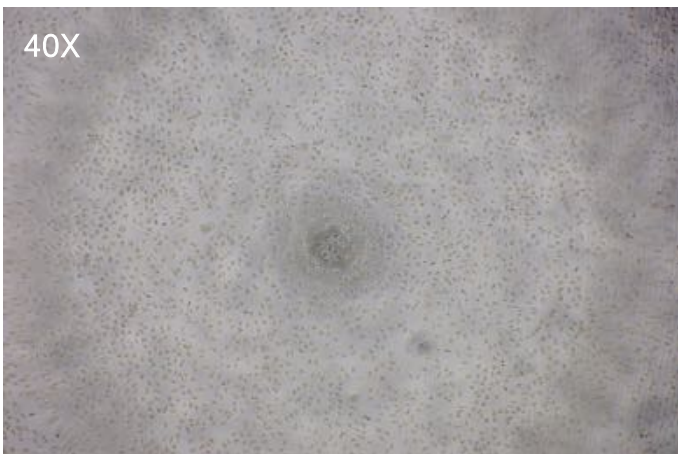
- DD GUIDE dental surgical guide (0)



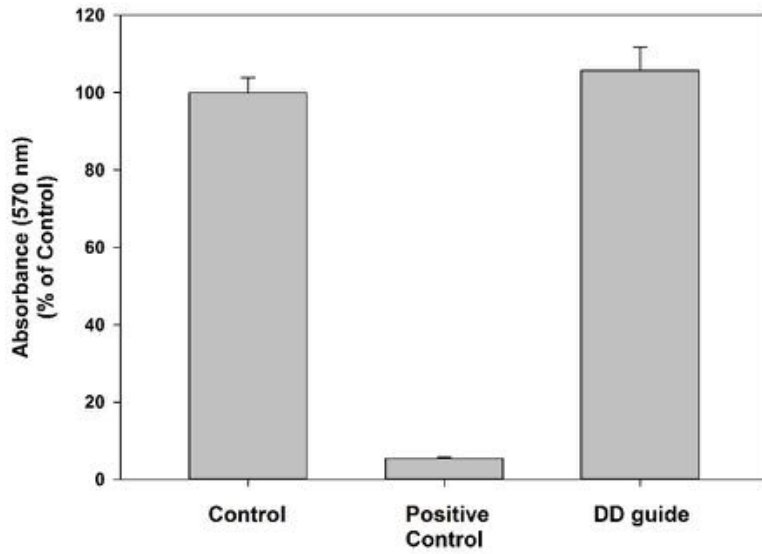
2. Negative Control (0)



3. Positive Control (4)



MTT cytotoxicity test



MTT test grading

Sample	Cytotoxicity (%)	MTT test grading
DD GUIDE dental surgical guide	-5,72%	0
Positive Control	94.55%	4

Grade: < 10% = 0 10~30% = 1 30~50% = 2 50~70% = 3 > 70% = 4

Company: Enlighten Materials Co., Ltd. 8F, No138, Jinshan South Road, Taipei, Taiwan

Emergency phone number: +886-988-661-609



MEDNET GmbH, Borkstraße 10, 48163 Münster, Germany
 Tel: +49 251 32266-0
 Fax: +49 251 32266-22
 E-mail: info@medneteuropa.com
 Website: www.medneteuropa.com