

DENTCA Crown and Bridge - Directions for Use

Intended Use for USA customers

DENTCA Crown and Bridge is a light-curable polymerizable resin to fabricate, by additive manufacturing, temporary crowns or bridges. The fabricated temporary crowns or bridges are an alternative to preformed temporary crowns or bridges.

The fabrication of temporary crowns or bridges with DENTCA Crown and Bridge requires digital models of crowns or bridges, a stereolithographic additive printer, and curing light equipment.

Intended Use for Canada customers

DENTCA Crown and Bridge is a light-curable polymerizable resin to fabricate, by additive manufacturing, temporary crowns or bridges to be used for less than 30 days. * The fabricated temporary crowns or bridges are an alternative to performed temporary crowns or bridges.

The fabrication of temporary crowns or bridges with DENTCA Crown and Bridge requires digital models of crowns or bridges, a stereolithographic additive printer, and curing light equipment.

*The device is registered in Canada as class II which is used for less than 30 days.

Requirements

1. Digital crown or bridge model file with minimum thickness 2mm; STL format file
2. Stereolithographic additive printer and its operation software;

Stereolithographic additive Printer		Operation Software	Provider
Product Name	Model		
Zenith	U	Zenith	Dentis -USA
SprintRay	MoonRay S100 or SprintRay Pro**	Rayware	SprintRay
Asiga	Max, Pro2 or Pro 4K	Asiga Composer	Asiga
Ackuretta	FreeShape 120	Alpha 3D	Ackuretta
WhipMix	VeriBuild	Alpha 3D	WhipMix

**Orienting printing model in Z direction or vertically to the platform is not recommended due to the SprintRay Pro printer is not supportive in that direction.

3. Curing light equipment

Curing Equipment	
Model	Provider
ECE 5000	Dymax
ELC 4001	Electro-lite

UV Sol 500/UVcube	Honle
Intelliray 600/SunRay 400	Uvitron
CUREBox Plus	Wicked Engineering
Pro Cure	SprintRay

Specific Manufacturing Considerations

1. Digital crown or bridge model file

1.1 File format: STL file

1.2 File size: less than 100 MB of each file

1.3 File size should be uploadable in the 3D printer operation software.

2. Stereolithographic additive printer

2.1 Hardware

a. Laser wavelength : 385 nm or 405 nm

b. Light source

- Stereolithographic (SLA) method; laser with $25 \text{ mW} < X < 250 \text{ mW}$
- Digital Light Processing (DLP) method; high power LED or lasers

c. Build Volume: $> 70 \times 50 \times 150 \text{ cm}$ (Least fit one arch)

d. Laser spot size (XY resolution): $< 160 \text{ micron}$

e. Build Speed: $1 - 1.5 \text{ cm/hr}$ at 50 micron and $1.5 - 4 \text{ cm/hr}$ at 100 micron

f. Build Path: line drawing path or surface layer drawing path

2.2 Features of Operation Software

a. STL file import

b. Automatic rotation and placement

c. Layer slicer for path inspection

d. Auto and manual generation of supports

2.3 Printing Parameters

Printer Model	Layer Thickness (micron)	Recommended orientation angle (degree)	Support point size (mm)	Support density
Zenith U	50-100	20-40	0.4 – 1.0	0.7 – 1.5
MoonRay S100 or SprintRay Pro	50	20-40	Medium	Medium
Asiga Max, Pro2 or Pro 4K	50-100	20- 90	0.7 -1.5	3.0 - 5.0 mm
Ackuretta FreeShape 120	50	20-40	1.5	70% - 80%
WhipMix VeriBuild	50	20-40	1.5	70% - 80%

2.4 Environmental Conditions

- a. Temperature: 18 – 30 °C
- b. Relative Humidity: 30 – 90 %

2.5 Cleaning Kit

Rinse bath and tubs, flush cutter, paper towel, squeeze bottle for isopropyl alcohol, Scraper

3. Recommended Curing light equipment (Post curing units)

3.1 Flood Type Curing Equipment

Provider/Model	Curing Chamber	Supply voltage (V / Hz)	Lamp power (W)	Light intensity (mW/cm ²)	Lamp wavelength (nm)	Curing time (min)
Dymax/ECE 5000	Required	100 – 240 /50 -60	400	225	UVA (365)	20
Electro-lite /ELC-4001	Required	110 or 220/65	400	125	UVA +UVV (365)	40
Uvitron/ Intelliray 600, SunRay 400	Required	100, 240 / 50 – 60	600, 400	175, 115	UVA (320-390)	20
Honle UV cure/Sol 500	Required	100 – 240 /50 -60	400	120	UVA+UVV	60
Wicked Engineering/ CUREBox Plus	Required	110-240 /50-60	36	12	UVA + UVV (365-405)	40
SprintRay/ Pro Cure	Required	110-240 /50-60	90	23	UVA + UVV (365-405)	40

3.2 Accessories

- a. USP Grade glycerin
- b. Transparent glass container and 2 glass plates
- c. Heat-protective gloves and silicone coated stainless steel tong
- d. Thermocouple

4. Notification

The device specifications have been validated using the software, printers, and process parameters specified in this document. Any other printers, operation software and post-printing processes will be outside of the device specifications and the FDA clearance. Users shall follow this document to use the device.

Warnings:

1. DENTCA Crown and Bridge resin contains polymerizable monomers which may cause skin irritation (allergic contact dermatitis) or other allergic reactions in susceptible persons. If contact with skin, wash thoroughly with soap and water. If skin sensitization occurs, discontinue use. If dermatitis or other symptoms persist, seek medical assistance.
2. Avoid inhalation or ingestion. High vapor concentration can cause headache, irritation of eyes or respiratory system. Direct contact with eyes may cause possible corneal damage. Long-term excessive exposure to the material may cause more serious health effects. Monitor air quality per OSHA standards.

Eye Contact: Immediately flush eyes with plenty of clean water for at least 20 minutes, and consult a physician. Wash the contacted area thoroughly with soap and water.

Inhalation: In case of exposure to a high concentration of vapor or mist, remove person to fresh air. Give oxygen or artificial respiration as required.

Ingestion: Contact your regional poison control center immediately

BURN HAZARD: GLYCEROL BATH CAN REACH TEMPERATURES OF 90 °C (~200 °F) AND LEAD TO SEVERE BURNS. Only trained users should perform the glycerol curing step with caution and appropriate PPE. We also recommend placing a warning label on the window of the cure unit to alert all lab users to the potential hazard.

Precautions:

1. When washing the printed crown and bridge with solvent or grinding the crown and bridge, it should be in a properly ventilated environment with proper protective masks and gloves.
2. Store DENTCA Crown and Bridge resin at or below 15 - 25 °C (60 -77 °F) and avoid direct sunlight. Keep container closed when it is not in use. Product shall not be used after expiration date.
3. Expired or unused DENTCA Crown and Bridge should be completely cured or polymerized prior disposal.

Adverse Reactions:

1. Direct contact with the uncured resin may induce skin sensitization in susceptible individuals.
2. Proper ventilation and personal protective equipment should be used when grinding printed crown and bridge as the particulate generated during grinding may cause respiratory, skin and eye irritation.

Procedure to Fabricate the Temporary Crowns and Bridges

1. Printing Preparation

- a. Select the tooth shade based on prescription. (Recommended to use the different resin tank or tray for the different shade.)
 - b. Open the 3D printer cover and fill the resin tank or tray of the printer with DENTCA Crown and Bridge resin up to the required filling line by manufacturer. (When filling the resin into the resin tank or tray, gloves and mask should be used.)
 - c. Close the printer cover.
2. Printing
- a. Load the crown or bridge model file to be printed in printer operation software which printer manufacturer recommended.
 - b. Use the printer operation software tool to rotate the model in order to locate the model in proper position to the build platform.
 - c. For the crown or bridge model, rotate the tip of teeth to face the build platform.
 - d. Generate support sticks on the model using the recommended setting by printer provider. If the support is not enough, add supports on the model. (Avoid the support structures on the connection area between teeth.)
 - e. Start printing.
3. Cleaning
- a. Detach the printed model from the build platform.
 - b. Use a small flush cutter to remove the support sticks from the printed model.
 - c. Wash the printed object with isopropyl alcohol.
 - d. Use air blowing to dry the printed object or dry it at room temperature under ventilation system or open area.
4. Post curing of printed object and finishing
- a. Smooth the support marks using a bur after washing the printed object with water and drying.
 - b. The printed one should be cured by soaking into the glycerin container for the required curing time under recommended post curing unit. (Glycerin temperature should be greater than 60°C and it is recommended the glycerin to replace every 80 hrs running or every three months whichever first.)
 - c. Take out the printed one from curing oven using coated tong (**Be careful hot glycerin!**).
 - d. Rinse the cured crowns and bridges with a water.
 - e. Polish the crowns and bridges with wet polishing sand by conventional method if needs.

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