

## DENTCA Crown and Bridge for Carbon Printers- Directions for Use

### Intended Use for USA customers

DENTCA Crown and Bridge for Carbon printers 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 for Carbon printers requires digital models of crowns or bridges, a stereolithographic additive printer, and curing light equipment.

### Intended Use for Canada customers

DENTCA Crown and Bridge for Carbon printers 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 for Carbon printers 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. Carbon Printer (M1 or M2) and Software
3. Dymax ECE 5000 with Hg Bulb or Dreve PCU LED

### Basic Material Properties

Characteristics/Properties	Units	Specification
<b>Before Curing (Liquid state)</b>		
Viscosity at 25 ±0.5 °C	cps	1000 < X < 2000
Density	g/cm <sup>3</sup>	1.05 < X < 1.20
Surface curing rate	second	< 2
Color L*	None	Varies according to the shade
Color a*	None	Varies according to the shade
Color b*	None	Varies according to the shade
<b>After Curing</b>		
Density	g/cm <sup>3</sup>	1.15 < X < 1.25
Flexural strength	MPa	50 < X
Degree of Conversion	%	70 < X
Shade	No difference	No perceptible color difference
Porosity	No porosity	No porosity or defect

## Specific Manufacturing Considerations

### 1. Digital crown or bridge model file

- 1.1 File format: STL file
- 1.2 File size should be uploadable in the Carbon printer operation software.

### 2. Carbon Printer (M1 or M2) and Software

#### 2.1 Hardware

- a. LED Wavelength: 385 nm
- b. Slice thickness: 100 micron (standard slicing) or 50 micron (fine slicing)
- c. Build Volume: M1: 141 x 79 x 326 mm; M2: 189 x 118 x 326 mm
- d. Pixel size: 75um

#### 2.2 Carbon, Inc. Software

- a. STL file import
- b. Rotation and placement
- c. View Slices
- d. Auto and manual generation of supports

#### 2.3 Printing Parameters

- a. Slice thickness: 100 micron or 50 micron
- b. Optimal Orientation: occlusal side of teeth facing platform with 30-45 degree tilt
- c. Support point size: varies based on support tip chosen
- d. Support density: support tooth cusp tips and ridges, overhang regions, and perimeter of bridges

#### 2.4 Environmental Conditions

- a. Temperature: 17 – 25 °C
- b. Relative Humidity: 30 – 70 %

#### 2.5 Cleaning and Bonding Kit

Personal Protective Equipment (PPE), tray, paper towels, foil, part removal tool, hand tools, 2 pairs of silicone tongs, isopropyl alcohol (IPA), labeled wash container, orbital shaker, timer, swabs, pipettes, cup, and soft silicone spatula

#### 2.6 Recommended Printer

- a. Carbon M1 or M2

### 3. Recommended Curing light equipment (Post curing units)

#### 3.1 UV curing Flood Type System

<b>Manufacturer/Model</b>	Dymax ECE 5000 with mercury vapor bulb (36970)	Dreve PCU LED
<b>Supply Voltage</b>	100-240VAC +/- 10% Single Phase	100-240V
<b>Lamp Power</b>	400 watt	18.5 mW/cm <sup>2</sup>
<b>Light Intensity</b>	>70 mW/cm <sup>2</sup> for Hg bulb in 320-395 nm range	410 nm
<b>Lamp Wavelength</b>	UVA (320-390 nm)	N/A
<b>Curing time</b>	20 min total (10 min on each side)	30 min total (no flipping since both sides cure simultaneously)

### 3.2 Accessories

- a. USP Grade glycerol ( $\geq 99.5\%$  purity, CAS# 56-81-5)
- b. Transparent glass container (recommend Pyrex Basics 2Qt dish: 11.1" x 7.1" x 1.7" when using Dymax or Circleware 23oz dish: 6" x 6" x 2.5" when using Dreve)
- c. 2 transparent glass plates (recommend McMaster-Carr Borosilicate Sheet - 9" x 9" x 1/8" when using Dymax or Sigma-Aldrich's Corning 75mm x 50 mm slides (CLS294775x50) when using Dreve)
- d. Large binder clip when using Dymax or electric hot plate, stainless steel pot with pouring spout, and electrical timer when using Dreve
- e. Thermocouple such as BENETECH GM1312 digital thermometer for K/J/T/E/R/S/N
- f. Heat-protective gloves
- g. Water

### 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 for Carbon printers 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 for Carbon printers 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 for Carbon printers 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 for Carbon printers 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 parts 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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