

DENTCA Denture Teeth for Carbon printers- Directions for Use

Prescription Use Statement

Caution: Federal law restricts this device to sale by or on the order of dentist or any other practitioner licensed by the law of the State in which he/she practices to us or order the use of the device.

Indications for Use

DENTCA Denture Teeth for Carbon printers is a light-curable polymerizable resin to fabricate, by additive manufacturing, preformed denture teeth to be used in a denture. The fabricated tooth is an alternative to preformed plastic tooth for denture.

The fabrication of denture tooth with DENTCA Denture Teeth for Carbon printers requires digital denture tooth files instead of physical molds, a stereolithographic additive printer, and curing light equipment.

Requirements

1. Digital denture tooth file in STL format
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
Before Curing (Liquid state)		
Viscosity at 25 ±0.5 °C	cps	1000 < X < 2000
Density	g/cm ³	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
After Curing		
Density	g/cm ³	1.15 < X < 1.25
Flexural strength	MPa	50 < X
Degree of Conversion	%	70 < X
Dimension of Teeth (XL anterior 6 teeth)	mm	50.24 < X < 51.76
Shade	No difference	No perceptible color difference
Porosity	No porosity	No porosity or defect

Specific Manufacturing Considerations

1. Digital denture tooth file

- 1.1 File format: STL file
- 1.2 Digital design: DENTCA BYTE tooth – Universal, Oval, and Square

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: roots side of teeth facing platform with 20 - 40 degree tilt
- c. Support point size: varies based on support tip chosen
- d. Support density: perimeter of denture teeth

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

Manufacturer/Model	Dymax ECE 5000 with mercury vapor bulb (36970)	Dreve PCU LED
Supply Voltage	100-240VAC +/- 10% Single Phase	100-240V
Lamp Power	400 watt	18.5 mW/cm ²
Light Intensity	>70 mW/cm ² for Hg bulb in 320-395 nm range	410 nm
Lamp Wavelength	UVA (320-390 nm)	N/A
Curing time	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, printer, and process parameters indicated and that any changes to the above will need to be re-validated to determine if design specifications are met. If changes are made that results in outputs that are outside of the design specification, FDA clearance will be needed.

Warnings:

1. DENTCA Denture Teeth 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.

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.

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.

Precautions:

1. When washing the printed denture teeth with solvent or grinding the denture teeth, it should be in a properly ventilated environment with proper protective masks and gloves.
2. Store DENTCA Denture Teeth 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 Denture Teeth II for Carbon printers shall be disposed in accordance with local regulations.
4. Glycerol and isopropanol shall be disposed in accordance with local regulations.

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 denture teeth as the particulate generated during grinding may cause respiratory, skin and eye irritation.

Procedure to Fabricate Teeth

1. Printing Preparation – See attachment for details.
 - a. Select the denture teeth shade based on prescription.
 - b. Wearing proper PPE, fill cassette with fresh DENTCA Denture Teeth for Carbon printers resin.
 - c. Close the printer door.
2. Printing (visit <https://print.carbon.com>) – See Carbon for training.
 - a. Upload the denture teeth model STL file into Carbon’s software.
 - b. Orient the teeth so that the root part of teeth (intaglio surface) faces the build platform.
 - c. Tilt the lingual side of teeth to around 20° to 40° against the build platform.
 - d. Generate fence supports around the perimeter of the denture teeth. Ensure none of the supports are placed above the gum line.
 - e. Start printing.
3. Cleaning – See attachment for details.
 - a. Remove the printed denture teeth from the build platform.
 - b. Wash the denture teeth with isopropyl alcohol (IPA) and remove remaining supports.
 - c. Ensure the denture teeth are dry before curing (such as compressed air, paper towels, or additional drying time at room temperature).
4. Teeth Post Curing (if not bonding to a DENTCA Denture Base II for Carbon printers denture base)
 - a. Smoothen the support marks using a bur or hand tool.
 - b. Cure the printed teeth by completely submerging in the glycerol container (glycerol temperature should be greater than 60°C) for 20 min in the Dymax ECE 5000, flipping the printed teeth over halfway through the post cure or 30 min under vacuum at 90% LED intensity in the Dreve PCU LED with no flipping (both sides cure simultaneously).
 - c. Use as preformed teeth to fabricate a denture by conventional denture process.

Denture Fabrication using printed denture teeth and base - See attachment for details.

1. Bonding the printed teeth to the printed denture base
 - a. Attention: Do not UV post-cure base or teeth prior to bonding step!
 - b. Prepare the teeth and base for bonding by removing any material from the teeth and denture base tooth sockets that impede tooth placement.
 - c. Place the printed teeth into the corresponding tooth sockets on the printed denture base and check teeth fitting.
 - d. Smoothen other support spots on the denture base using a bur or hand tool.
 - e. Apply a small amount of shade-matched light curable adhesive (DENTCA Denture Base II Carbon printers) into the tooth sockets and bond teeth by exposing to UV light until the teeth set in position. Recommended to use DENTCA Denture Base II for bonding.
 - f. If necessary, apply a small amount of shade-matched DENTCA Denture Base II for Carbon printers using an applicator to smoothen the edges of the denture base and cure it.

2. Post Curing

- a. Cure the final denture by completely submerging in the glycerol container (glycerol temperature should be greater than 60°C) for:
 - i. 20 min in the Dymax ECE 5000, flipping the dentures over halfway through the post cure
 - ii. 30 minutes under vacuum at 90% LED intensity in the Dreve PCU LED with no flipping (both sides cure simultaneously).

3. Finishing

- a. Polish the final denture with wet polishing sand by conventional method.