DENTCA Denture Teeth - Directions for Use

The acquisition of this product for the purpose of distribution or reselling without DENTCA's authorization is prohibited.

Indications for Use

DENTCA Denture Teeth 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 requires digital denture tooth files instead of physical molds, a stereolithographic additive printer, and curing light equipment.

Requirements

1. Digital denture teeth file; 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	DENTIQ (formerly known as FreeShape 120) or SOL	Alpha 3D	Ackuretta
WhipMix	VeriBuild or VeriEKO	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

Otoflash G171	NK-Optik
PHOTOPOL A5408D	Dentalfarm
CURIE	Ackuretta
ProCure 2	SprintRay
VeriLUX	WhipMix

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

1.3 File size should be upload-able 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 mW < X < 250 mW
   - Digital Light Processing (DLP) method; high power LED or lasers
c. Build Volume: > 70 x 50 x 150 cm (Least fit one arch)
d. Laser spot size (XY resolution): < 160 micron
e. Build Speed: 1 – 1.5 cm/hr at 50 micron and 1.5 - 4 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 Parameter

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	20-40	0.8	Spacing 3.0mm

Ackuretta DENTIQ (formerly known as FreeShape 120) or SOL	50-100	20-40	1.5	70% - 80%
WhipMix VeriBuild or VeriEKO	50-100	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

2.6 Recommended Printer

a. Zenith U Printer, MoonRay S100 and SprintRay Pro Printers, Asiga Max, Pro2 and Pro 4K Printers, Ackuretta DENTIQ (formerly known as FreeShape 120) and SOL Printers, WhipMix VeriBuild and VeriEKO Printers

3. Recommended Curing light equipment (Post curing units)

3.1 Flood Type Curing Equipment

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

NK-Optik/ Otoflash G171	Required	100, 117, 230VAC/50-60Hz	200W	50 mW/cm^2	UVB + UVA + UVV (280-580nm)	**10 min**
Dentalfarm/ PHOTOPOL A5408D	Required	100, 117, 230VAC/50-60Hz	50W	100 mW/cm^2	UVA + UVV (350-550nm)	**40 min**
Ackuretta/ CURIE	Required	100-240VAC/50-60Hz	70W	190 mW/cm^2	UVA + UVV (365-405nm)	**10 min (T:10, D:10, I:13, B:ON)**
SprintRay/ *ProCure 2	Required	100-240V/50-60Hz	150W	>50 mW/cm^2	UVA (385nm)	**Default Setting (9:47, Zone A&B)**
WhipMix / VeriLUX	Required	100-240VAC/50-60Hz	70W	190 mW/cm^2	UVA + UVV (365-405nm)	**10 min (T:10, D:10, I:13, B:ON)**

*No flip required during curing

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

4.1 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.

4.2 If there is any serious incident (death or permanent damage to a patient) that has occurred in relation to this device, please report to DENTCA (info@dentca.com) or your local authority of medical device.

4.3 When you receive the damaged or unintentionally opened bottles before use, or if the packaging is exposed to environmental conditions outside of the specified in the label, please inform to DENTCA (info@dentca.com).

Warnings:

1. DENTCA Denture Teeth 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 denture teeth with isopropyl alcohol or grinding the denture teeth, it should be in a properly ventilated environment with proper protective masks and gloves.
2. Store DENTCA Denture Teeth at 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 should be completely cured or polymerized prior to 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 denture teeth as the particulate generated during grinding may cause respiratory, skin or eye irritation.

Procedure to Fabricate Teeth

1. Printing Preparation
   a. Select the denture teeth 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 Denture Teeth 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 denture teeth model file to be printed in printer operation software which printer manufacturer recommended.
   b. Use the software tool to rotate the teeth in order to face the root part of teeth to the build plate form.
   c. Tilt the lingual side and root of teeth to around 20 to 40 degree against the build plate form.
   d. Generate support sticks on the denture teeth using the recommended setting by printer provider. If the support is not enough, add supports on the teeth. (Avoid the support structures on the valley between teeth.)
   e. Use layout tools to move the denture teeth to be evenly distributed.
   f. Start printing.

3. Cleaning
   a. Detach the printed denture teeth from the build platform.
   b. Use a small flush cutter to remove the support sticks from the denture teeth.
   c. Wash the denture teeth with isopropyl alcohol.
   d. Use air blowing to dry the denture teeth or dry it at room temperature under a ventilation system or open area.

4. Teeth Post Curing
   a. Smooth the support marks using a bur after washing the teeth with water and drying.
   b. For printed denture fabrication, skip this post-curing step and move to “Denture Fabrication using printed teeth and base” step.
      For conventional fabrication to use as preformed teeth, the printed teeth should be cured by soaking into a glycerin container for the required curing time under the recommended post-curing unit.
   c. Use the printed preformed teeth to fabricate a denture by conventional denture process.

Denture Fabrication using printed denture teeth and base

1. Bonding the printed teeth to the printed denture base
   a. Prepare, before post-cured, the printed teeth and printed denture base with socket shapes to receive printed teeth (Tooth Sockets).
   b. Place the printed teeth into the corresponding Tooth Sockets on the printed denture base and check teeth fitting.
   c. Apply small amount of light curable adhesive into the Tooth Sockets and bond the teeth by exposing into UV light until the teeth is set in position. Recommend using DENTCA Denture Base II, DENTCA Base Premium or DENTCA Base Hi-Impact as an adhesive to bond the printed teeth.
   d. If necessary, apply small amount of the same denture Base resin using an applicator to smoothen the edges of the denture base and cure it.

2. Post Curing
   a. Cure the final denture according to the following table for the required curing time inside the recommended post-curing unit.

Denture Base Material	Curing Condition
DENTCA Denture Base II	Sink the final denture into the glycerin container, place it in the curing unit and cure it for the required curing time
DENTCA Base Premium or DENTCA Base Hi-Impact	Place the final denture in the curing unit without soaking into the glycerin and cure it for the required curing time

   For post-curing time, tissue side up and for the other half of the time tissue side down.
   Note: Glycerin temperature should be greater than 60°C and it is recommended to be replaced every 80 hrs or every three months whichever comes first.
   b. Take out the printed denture from the curing oven using coated tong (**Be careful of hot glycerin and object!**).
   c. Rinse the cured denture according to the following table.

Curing Condition	Rinsing Condition
With glycerin (DENTCA Denture Base II)	Rinse the denture with water.
Without glycerin (DENTCA Base Premium and DENTCA Base Hi-Impact)	Rinse the denture with isopropyl alcohol, and then rinse with water.

3. Finishing
   a. Smoothen the support spots on the denture base using a bur.
   b. Polish the final denture with wet polishing sand by a conventional method.