DENTCA Try-In 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 Try-In is a light-curable resin indicated for fabrication and repair of full and partial removable dentures and baseplates. The material is an alternative to traditional heat-curable and auto polymerizing resins.

Fabrication of dental prosthetics requires a computer-aided design and manufacturing (CAD/CAM) system that includes the following components: digital denture files based on a digital impression, stereolithographic additive printer, and curing light equipment.

DENTCA Try-In is particularly suitable to fabricate the try-in denture before installing a final denture.

Requirements

1. Digital denture model file; STL format file with following minimum thickness of the area

Area	Maxillary	Mandibular
Lingual Ridge area	≥ 2.5 mm	≥ 2.5 mm
Palatal/Lingual	≥ 2 mm (≥3 mm single Arch upper)	≥ 2 mm
Facial/Buccal	≥ 2 mm	≥ 2 mm
IOD* area	≥ 2.5 mm	≥ 2.5 mm

* IOD: Implant Over Denture

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

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 model file

1.1 File format: STL file

1.2 Digital design: Denture design file with characteristic features of denture and the following minimum thickness

Area	Maxillary	Mandibular
Lingual Ridge area	≥ 2.5 mm	≥ 2.5 mm
Palatal/Lingual	≥ 2 mm (≥3 mm single Arch upper)	≥ 2 mm
Facial/Buccal	≥ 2 mm	≥ 2 mm
IOD* area	≥ 2.5 mm	≥ 2.5 mm

* IOD: Implant Over Denture

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 Parameters

Printer Model	Layer Thickness (micron)	Recommended orientation angle (degree)	Support point size (mm)	Support density
Zenith U	50-100	20 -60	0.4 – 1.0	0.7 – 1.5
MoonRay S100 or SprintRay Pro	50	45- 90	Medium	Medium
Asiga Max, Pro2 or Pro 4K	50-100	20- 90	1.2 - 1.5	Spacing 5.0 mm
Ackuretta DENTIQ (formerly known as FreeShape 120) or SOL	50-100	30- 90	1.2 - 1.5	70% - 80%
WhipMix VeriBuild or VeriEKO	50-100	30- 90	1.2 - 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	100-240 V/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 Try-In 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 try-in denture with isopropyl alcohol or grinding the try-in denture, it should be in a properly ventilated environment with proper protective masks and gloves.
2. Store DENTCA Try-In resin 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 Try-In 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 try-in denture as the particulate generated during grinding may cause respiratory, skin or eye irritation.

Procedure to fabricate try-in denture

1. Printing Preparation
   a. Open the 3D printer cover and fill the resin tank of the printer with DENTCA Try-In up to the required filling line by manufacturer. (When filling the resin into the resin tank, gloves and mask should be used.)
   b. Close the printer cover.

2. Printing
   a. Load the denture model file to be printed in printer operation software which printer manufacturer recommended.
   b. Use auto-orientation or manual orientation to find its optimal position for printing. The recommended orientation by printer provider is a tilted orientation such as space diagonal from 20 to 90 angle. If auto-orientation is not satisfied, rotate to make optimal position.
   c. Generate support sticks on the denture model. If the support is not enough, add supports on the denture model.
   d. Use layout tools of the software to move the denture base model within the imaginary build platform to prevent the overlapping between models.
   e. Start printing.

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

4. Post Processing of try-in denture
   a. Add DENTCA Try-In material manually on the lingual ridge area to thicken and cure it. It is recommended to make it thicker than 4.0mm for maxillary and 4.5mm for mandibular.
   b. Cure the printed try-in denture by sinking into glycerin container for the required curing time under recommended post-curing unit. For half of the post-curing time tissue shall side up and for another half of the time tissue shall side down.
   Note: It is recommended the glycerol to be replaced every 80 hrs of running or every three months whichever comes first.

c. Take out the printed denture from the curing oven using coated tong (**Be careful of hot glycerin!**).
d. Rinse the cured denture with water.
e. Smooth the support marks using a bur after washing the try-in denture with water and drying.
f. Please make sure all the support marks are completely grinded.