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Instructions for use



CRS® Custom Denture Resin

Printer compatibility 385 nm / 405 nm

Description:

The instructions for use are for dental professionals who use Custom Denture Resin as a material for denture bases.

This instruction for use also provides information about tips&tricks, safety and environmental aspects. In case more information is needed, contact the reseller.

Custom Denture Resin is provide light-curing 3D printable resin-based materials for the correction or reconstruction of functionally compromised natural dentition (e.g., missing teeth or deficient teeth) by manufacturing of customized 3D-printed dental prostheses.

It is intended exclusively for professional dental work.

Indications for Use:

Custom Denture Resin is a light-curable polymerizable resin intended to be used for the fabrication and repair of full and partial removable dentures and baseplates. The material is an alternative to traditional denture base material.

Contraindications:

Custom Denture Resin must not be used for any other purposes than those specified in the "Indication" section.

Any deviation from this instruction for use may have negative effects on the chemical and physical quality of the restorations produced from Custom Denture Resin.

Do not use the product in case of a known allergy to one or more ingredients.

In case of doubt, clarify and exclude a possible allergy with the help of a specific allergy test before using Custom Denture Resin.

Custom Denture Resin is contraindicated when there is direct intraoral contact with resin that is not fully cured.

In case of an allergic reaction, please contact a medical physician.



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Notes:

Custom Denture Resin is intended to be used in combination with DLP and LCD based 3D printers that support CRS resins.

Printer and resin must be optimized to each other in order to produce complete and precise printed parts. If the printer and resin are not optimized with respect to each other this may have an adverse effect on the accuracy and physical quality of printed parts.

CRS shall not be held liable for any damage caused by misuse.

Always keep bottle tightly closed, carefully close immediately after each use.

Product may cause allergic reactions.

Warning and Precautions:

Custom Denture Resin is a non-toxic material after the proper printing and post-processing procedures. **Skin Contact:** May cause skin irritation. If unprocessed resin contacts skin, wash thoroughly with soap and water. May cause an allergic skin reaction. If skin sensitization occurs, stop using. If dermatitis or other symptoms persist, seek medical assistance.

<u>Inhalation:</u> High vapor concentration may cause headache, irritation of eyes and/or respiratory system. If exposed to a high concentration of vapor or mist, move to fresh air. Use oxygen or artificial respiration as required.

Eye Contact: Wash the contacted area thoroughly with soap and water.

Ingestion: Contact and seek medical assistance immediately.

Fabrication of Device:

Design:

The data to be produced must be prepared in .stl format with the support of CAD software by the relevant person.

These device specifications have been validated using the following manufacturing products. Any products or processes not specified in this document are outside of the devicespecifications. CAD file of treatment device in STL file format with the following thickness:

Area	Maxillary	Mandibular
Lingual ridge	≥ 2.5 mm	≥ 2.5 mm
Palatal/lingual	≥ 2 mm	≥ 2 mm
Facial/buccal	≥ 2 mm	≥ 2 mm
Implant Overdenture area	≥ 2.5 mm	≥ 2.5 mm



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Support and Nesting:

The layout and support settings in the slicer program should be configured according to the support settings prepared or recommended by CRS for the specific design you will be printing. In case more information is needed, contact the reseller.

Note:

The side that will sit on the palate should be facing the build platform. 60 degree angle, the back surface should be closer to the build platform.

Print:

Ensure the 3D printer is clean prior to use, including the imaging area and any optical surfaces. Ensure the resin tray is clear of solid debris prior to commencing a print. The presence of solid particles in the resin may cause deformation or failure of the printed objects.

Nitrile gloves should be worn at alltimes when handling CRS liquid resins up until the finishing step. Avoid contact with skin.

Mix Before Use:

Shake bottle mightily prior to pouring for at least one minute.

Stir material with a soft spatula. Take care not to damage the bootm of the resin tray. This step is necessary to re-disperse the (possible) pigment sediment from the bottom of the vessel. Colour deviation and print failures may occur if insufficiently mixed.

Fill Resin Tray:

Ensure the temperature of the resin is between 22 and 30°C (68 and 86°F) and prevent exposure to direct sunlight. Pour the resin into the resin tray of the 3D printer.

Printer Settings:

Custom Denture Resin is optimised to build parts using light with 385nm or 405nm wavelength.

You need to use the customized and validated resin profile settings for LCD or DLP technology printers. You must ensure the calibration and light intensity accuracy of the 3D printers you are using for measurement precision.

You can find the recommended profile settings from CRS on the website or through the dealer. Ensure the film of the resin tray is clear of any debris before starting the print.



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Part and Support Removal:

After your device has been printed, remove it from the print platform using the provided print removal tool. Remove all supports using a flush cutter or round disc. Cut as close as possible to the the printed part to minimize the smoothening and finishing procedure.

If Print Fail:

Remove the resin tray from the printer and filter the resin through a fine 190 Micron paint strainer, if:

- print has failed partially or completely,
- particulates of polymerized residues are visible in the container or stick to the bottom.

Wash:

Wash parts in at least 98% pure isopropyl alcohol (IPA) in a well ventilated area.

Best results are achieved when using a pre and post wash.

Using an ultrasonic cleaning device or alternatively, devices that create a vortex for washing are recommended:

- Pre-wash bath: 210 seconds.
- Post-wash bath: 180 seconds.

Note 1: After each washing process, follow by using compressed air to thoroughly dry the printed part, and then assess the cleanliness of the surface.

Note 2: Ensure a dedicated IPA bath is used for washing Custom Denture parts. Do not wash in IPA that has previously been used for washing other materials. Wiping any resin residue away with a dry cloth is permitted should there be any remaining after the IPA washing steps. Allow parts to dry thoroughly before post-curing

Note 3: For fine cleaning after post-washing, a toothbrush should be used.

Post-Cure:

Post-curing is an UV-light treatment to ensure that Custom Denture printed parts obtain optimal polymer conversion. Through this the residual monomer is reduced to a minimum and the required mechanical properties are obtained.

Curing devices show different performances based on their features. Curing processes conducted in an inert environment yield more successful results.

This document provides separate information regarding the devices for which we have completed CRS tests. The recommended devices are ranked according to their performances.



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Note: Allow parts to dry thoroughly before post-curing. After washing and drying, let the printed parts rest for at least 8 minutes to ensure that the printed parts are free of alcohol residue.

1-NK Optik Otoflash G171:

- 1- Place the printed parts in UV curing unit "NK Optik Otoflash G171" for 5000 flashes.
- 2- Turn parts over and allow to cool.
- 3- The same process for the second time in the 5000 flashes (Total: 2 x 5000 flashes).
- 4- Allow to cool

Note: We advise use of the NK Optik Otoflash G171 post-curing box. Place parts inside the G171 Otoflash chamber on the support mesh, do not use a plastic tray inside the chamber.

- 2-Trasformer Light Box:
- 1- Place the printed parts in UV curing unit "Trasformer Light Box" for 5.5 minutes programme.
- 2- Turn parts over and allow to cool.
- 3- The same process for the second time in the 5.5 minutes program
- 4- Allow to cool

Note: We recommend using the "Transformer Light Box" device for the recommended durations in an inert environment.

- 3- Dentalfarm Photopol:
- 1- Place the printed parts in UV curing unit "Dentalfarm Photopol" for 10 min, 120 % + N2
- 2- Turn parts over and allow to cool.
- 3- The same process for the second time in the 10 min, 120 % + N2
- 4- Allow to cool

Note: We recommend using the "Dentalfarm Photopol" device for the recommended durations in an inert environment.

4-Medifive Twin Cure:

- 1- Place the printed parts in UV curing unit "Medifive Twin Cure" for 25 minutes programme.
- 2- Turn parts over and allow to cool.
- 3- The same process for the second time in the 25 minutes programme
- 4- Allow to cool

Note: "Medifive Twin Cure" device operates at a wavelength of 365-405 nm, so we recommend extending the duration of the curing process.



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5-Solidilite V:

- 1- Place the printed parts in UV curing unit "Solidite V" for 4.5 minutes programme.
- 2- Turn parts over and allow to cool.
- 3- The same process for the second time in the 4 minutes program
- 4- Allow to cool

Note: "Solidite V" device operates with 4 units of 150-watt halogen lamps. It is among the validated devices due to being a product that many laboratories have previously purchased.

- 6-Affordable Price Curing Units:
- 1- Place the printed parts in UV curing unit "Phorozen, Anycubic etc.." for 40 minutes programme.
- 2- Turn parts over and allow to cool.
- 3- The same process for the second time in the 40 minutes programme
- 4- Allow to cool

Note: "Medifive Twin Cure" devices operates at a wavelength of 405 nm, so we recommend extending the duration of the curing process.

Finish Glaze:

The prosthesis produced can be characterized and polished using common polishing kits or can be polished according to the patient's aesthetic needs with a laboratory hand tool and lathe. All opti glaze products can be used for glaze application regardless of brand. In addition, the transparent Custom Glaze product produced by CRS can be used for surface gloss without coloring purpose.

Finishing&Polishing:

Prepare the restoration with 40 μ and 12 μ diamond burs. Polish to a high gloss using polishing brushes, polishing discs, strips or silicone polishers.

You may use a pink compound bar and cotton buff to achieve a mirror finish.

Inserting of artificial teeth in the printed, prefabricated prosthesis base:

Roughen the base surface of the printed artificial teeth for example by sandblasting, apply a primer and a fixing material, insert in the prosthesis according to the natural shape and polymerise.

Alternatively, Custom Denture can also be used directly as fixing material. For this purpose, put a small amount of material with a brush on the roughened teeth-surface of the artificial tooth, put it into the prosthesis, eliminate any excess material and light cure it from all sides for at least 20 seconds. The polymerisation lamp should work in the range of 320 to 500 nm and have at least a light output of 600 mW/cm²



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Before delivery to the clinic:

Use a laboratory steamer to clean the denture of all debris and polishing compounds. Usesoapand a brush with warm water.

Patient use hygiene:

Prosthesis bases made of DENTURETEC should not be cleaned with chemical products. Cleaning with water is sufficient. The finished restorations can - if necessary - be disinfected with an ethanol solution.

Storage Conditions, Expiry Date & Transport:

Store the resin in the original packaging at room temperature in a dry, cool and dark area. Close the packaging after each use.

To protect against contamination, cover the material in the resin tray with the lid or a glass plate.

The expiry date of the product is mentioned on the product label along with the lot number.

The standard shelf life is up to 4 weeks in the printer with the cap on, or up to 2 years in the bottle in a cool, dark place without opening the cap.

The product performance is no longer guaranteed once the expiry date is exceeded. Do not expose to UV-light.

Standard transport conditions apply to this product. There are no restrictions for transport related to hazardous substances.



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Disposal:

Custom Denture Resin in its polymerized form is not environmentally harmful thus can be disposed of in general waste.

Custom Denture Resin in its liquid state should be treated as chemical waste. Special disposal requirements are applicable, check with your local, federal, or other regulatory agencies for disposal requirements.

Delivery Units:

Custom Denture Resin is available in 3 colours: Pinkish, Reddish and Blackish Ordering Information: 1000 gr, 500 gr, 250 gr

