

# Instructions for use

Rev 02 09/2024

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## CRS® Custom Splint Resin

Printer compatibility 385 nm / 405 nm

### Description:

The instructions for use are for dental professionals who use Custom Splint Resin as an alternative to traditional hard occlusal guard material that is intended exclusively for professional dental work. This instruction for use also provides information about tips&tricks, safety and environmental aspects. In case more information is needed, contact the reseller. It is intended exclusively for professional dental work.

### Indications for Use:

Custom Splint Resin is a biocompatible photopolymer resin intended for the fabrication of orthodontic and dental appliances such as mouthguards, nightguards, splints, repositioners and retainers. Custom Splint Resin is a liquid photopolymer resin designed for additive manufacturing in vat Polymerization DLP printers utilizing wavelengths between 385nm-405nm. Characterized by its flexural strength and hardness, Custom Splint Resin is a material designed for 3D printing of orthodontic and dental appliances.

### Contraindications:

Custom Splint 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 Splint 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 Splint Resin.

Custom Splint 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 Splint 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 Splint 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.

**Inhalation:** 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 device specifications.

Minimum material thickness for the design: 1,1 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:** It is recommended that the prosthesis be placed on the build platform in a way that does not provide support to the areas where it will fit onto the teeth.

Placing it at a 60 degree angle and with minimum support option will yield successful results.

### **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 all times 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 bottom 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 Splint 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 smoothing 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: 150 seconds.
- Post-wash bath: 120 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 Splint 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.

**Note 4:** In total, the print should spend no more than 5 minutes in alcohol to avoid microcracks and abrasions. Once cleaned, air-dry the print using compressed air. If the model feels tacky to the touch or has a shine, dunk it in IPA a few more times until the excess resin is totally removed.

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### Post-Cure:

Post-curing is an UV-light treatment to ensure that Custom Splint 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.

**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- Dentalfarm Photopol:

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

**Note:** We recommend using the “Dentalfarm Photopol” device without nitrogen.

### 2-Trasformer Light Box:

- 1- Place the printed parts in UV curing unit “Trasformer Light Box” for 1.5 minutes programme.
- 2- Turn parts over and allow to cool.
- 3- The same process for the second time in the 1 minute program
- 4- Allow to cool

**Note:** We recommend using the “Transformer Light Box” device without nitrogen.

### 3-NK Optik Otoflash G171:

- 1- Place the printed parts in UV curing unit “NK Optik Otoflash G171” for 600 flashes without nitrogen.
- 2- Turn parts over and allow to cool.
- 3- The same process for the second time in the 600 flashes without nitrogen (Total: 2 x 600 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.

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### 4-Medifive Twin Cure:

- 1- Place the printed parts in UV curing unit "Medifive Twin Cure" for 8 minutes programme.
- 2- Turn parts over and allow to cool.
- 3- The same process for the second time in the 8 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.

### 5-Solidilite V:

- 1- Place the printed parts in UV curing unit "Solidite V" for 1 minute programme.
- 2- Turn parts over and allow to cool.
- 3- The same process for the second time in the 1 minute 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 10 minutes programme.
- 2- Turn parts over and allow to cool.
- 3- The same process for the second time in the 5 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.

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### **Finishing&Polishing:**

Use low RPM with an abrasive wheel or carbide bur to remove any stumps from supports. Use 10,000-12,000 RPM.

Use a steamer or rinse the splint with warm soapy water. Brush with a toothbrush to remove residue.

### **Patient Try-in and Adjustment:**

Soak the guard in a bowl of warm water no hotter than 50°C for 15 seconds to soften.

Seat the guard and let the patient try the appliance. Adjust contacts chairside.

### **Before delivery to the clinic:**

Use a muslin wheel and pumice on a dental lathe with firm, consistent pressure. Reach all areas of the guard. Keep the wheel damp and the pumice flowable.

Use a fresh muslin wheel and Tripoli. Use firm and consistent pressure, reaching all areas of the guard. Once finished, apply again and repeat using light pressure.

Use a fresh muslin wheel and Hatho beige. Use firm and consistent pressure, reaching all areas of the guard. Achieve a uniform shine across the full appliance.

### **High Gloss (Optional):**

Use a cotton buff wheel and Hatho pink. Use consistent pressure, reaching all areas of the guard until you achieve a mirror finish. Use a toothbrush with warm soapy water and/or a steamer to disinfect the guard before delivering it to the patient

### **Patient use hygiene:**

The appliance fabricated with Custom Splint Resin is a customized singlepatient, multi-use oral appliance that should be cleaned between uses.

The patient can clean the appliance with soap and warm water, or any over-the-counter cleaning agent indicated for oral devices.

Do not soak the finished appliance longer than 3 hours.

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### **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.

### **Disposal:**

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

Custom Splint 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 Splint Resin is available in 1 colour: Clear

Ordering Information : 1000 gr, 500 gr, 250 gr