RODIN Sculpture Resin

Instructions For Use Guide

1. Device Description

Rodin Sculpture Ceramic Nano-hybrid Resin is a biocompatible, Class II, light-curable resin indicated for prescribed fabrication of fixed, long-term crowns, bridges (full and partial denture teeth included), inlays, onlays, and veneer restorations using 3D printing technology.

2. Composition

Rodin Sculpture Ceramic Nano-hybrid Resin is comprised of a Dimethacrylate based resin, photo initiator, inhibitor, fumed silica, and pigments. It utilizes the same resin components found in typical dental restorative composites.

3. Intended Customer

Rodin Sculpture Ceramic Nano-hybrid Resin is intended to be used only by trained professional dentists or dental lab technicians. All sales are restricted to dental supply dealers, teaching institutions and government dental facilities. This product is labeled for sales restricted to dentists (or properly licensed practitioner).

4. Intended Use

For fabrication of crowns, bridges, inlays, onlays, veneers, partial and full denture arches. **Rodin Sculpture** Nano-hybrid Ceramic Resin requires a computer-aided design and manufacturing (CAD/CAM) system includes the following components not part of the device: oral casting impression, digital restorative file created from an optical impression system, stereolithographic additive printer, and curing light equipment. For use in tandem with validated 3D printers and post-curing devices listed below while following manufacturer's suggested instructions.

5. Contraindications

Rodin Sculpture is not recommended for the following prescribed restorations:

5.1 Anterior, posterior, or a combination of both posterior and anterior bridges should not exceed 3 units.
5.2 Posterior bridges with connector areas of < 27mm (H=3mm x D=3mm).
Anterior bridges with connector areas of < 12mm (H=3mm x D=2mm).
5.3 Cantilevered or Maryland bridges.

5.4 Bridges including rests or PD attachments.

5.5 Patients diagnosed with bruxism.

Note - A minimum thickness of 1mm is recommended on posterior occlusal and axial wall areas for all crown, bridge, onlay, and inlay designs. All anterior designed crowns and bridges are recommended to have a minimum buccal wall thickness of 1mm with the exception of veneers where the minimum buccal wall thickness is set at 0.5mm and incisal area at 1mm.

6. Orientation & Supporting

6.1 Best practices for nesting crowns and bridges are to orientate parts upside down where the supports will contact the occlusal and incisal surfaces. Placing supports in cavity should be avoided.

6.2 The recommended minimum support diameter is 0.27mm at the point of contact where the support meets the restoration.

6.3 The recommended minimum support height is 2mm to prevent breakage during removal of restoration(s).

7. Mixing

3D printing resins contain chemicals of different weights; therefore, it is essential to thoroughly mix the resin prior to starting a new print job.

7.1 For resin already in the resin vat, use a silicon blade to gently stir in settled ceramic fillers at the bottom of the resin tank.

7.2 Before dispensing the resin from the bottle, use a plastic spatula to stir the bottom of the bottle for several minutes before dispensing or mix using an automated bottle roller for 30 minutes.

7.1 If the bottle has been in storage for excess of a month, it is recommended to roll the bottle for 1 hour to allow ceramic fillers to reintegrate back into suspension.

8. Post-processing Instructions

8.1 After completion of the print job, remove the build platform from the 3D printer.

8.2 Using low pressurized air, blow away excess uncured resin from the printed model and build plate. Do not reuse excess resin if the build plate is made of aluminum. Contamination may occur and change color properties of the resin.

8.3 Using a blade, carefully remove the model from the build platform by sliding the blade under the base of the print closest to the build plate and work around the base until the print is removed.

8.4 DO NOT submerge restorations in isopropyl alcohol (IPA) for any amount of time.
To remove excess resin, wet paper towel or cloth with 99% IPA (optimal concentration) and wipe restoration clean. Clean between the embrasures, anatomical grooves and internal cavities of the restoration using a regular or electric tooth brush. Repeatedly dip the head of the toothbrush in IPA and scour the restoration as needed. A white chalky surface will appear if the printed restoration has incurred excessive exposure to IPA upon drying.

8.5 Use compressed air to remove excess uncured resin.

8.6 Repeat steps 8.4 and 8.5 until the restoration is thoroughly clean leaving a chalk-free, matte finish.

8.7 Post-cure all shades in a validated UV LED light-cure heat-cure box following recommended time and temperature schedules.

8.8 Once print has been post-cured, the restoration can be finished and polished using traditional dental tools and techniques.

9. Validated 3D Printers

9.1 Asiga Max (385nm), Asiga Pro4k (385nm), Asiga Pico2 (385nm)

9.2 Ackuretta SOL

9.3 Phrozen Sonic 4k, Phrozen Sonic Mini 4k

10. Validated Light Curing Devices

10.1 **Otoflash (recommended)** - 4500 flashes**

10.2 Dreve PCU LED N2 – 15min @ 40%**

10.3 Ackuretta Curie – 20min, P9, D2, BL ON

10.4 Formlabs Form Cure – 10min @ 40C

** Post curing under vacuum or with inert gas is recommended if applying light cured stains and/or glaze to fully cure surface and increase durability.

11. UV Glazing/Conventional Polishing

11.1 Apply a thin layer of UV glaze to a restoration or an assembled denture when in green state. Post cure as directed (see section 9).

11.2 For crown and bridge, post cure restoration as directed prior to polishing. Remove XY build layer lines with an abrasive acrylic polishing compound. Steam off residual compound, then finish with a silicone impregnated high shine wheel.

For a denture, post cure assembled denture as directed prior to polishing. Remove XY build layer lines with wet pumice and rag wheel technique. Next, high shine with acrylic polishing compound and rag wheel. Steam off residual compound once completed.

12. Chairside Adjustments and Cementation

12.1 If making chair side adjustments, treat the restoration like a composite and use carbide burs to remove material and buff with acrylic polishing compounds to regain luster to adjusted areas.

12.2 Recommended to use dual cure composite cement systems. Follow preferred manufacturer's instructions as directed.

13. Environment Conditions

13.1 3D photopolymer resins are very light-sensitive, sensitive to ambient office lights and sunlight from a window. Do not leave resin bottles open. Resin that has been poured into a resin tank should be covered if not used.

13.2 Best to store resin between 65F and 85F. Printing temp should be set to 30 degrees Celsius for optimum performance if applicable. If the bottle is stored in colder lab conditions as indicated above, it is recommended to place resin bottle with lid tightly sealed in a warm water bath.

14. Nightly/Long-term Storage

At the end of the day, it is best to pour unused resin from the printer back into the resin bottle for storage. When pouring resin from your tank or other vessel back into the bottle, always pour through a fine mesh filter. This will trap partially-cured debris and prevent

contamination of the rest of your bottle, prolonging the life of your materials. The resin is best stored in its original container to maintain shelf-life.

15. Disposal

Dispose in accordance with all federal, state and local regulations. Consult state and local hazardous waste regulations to ensure complete and accurate classification of waste. US EPA guidelines for the classification of hazardous waste are found in 40 CFR part 261.3. Liquid resin should be cured before being disposed of. Pour liquid resin into a clear container and set it in direct sunlight. Once it has cured, it can be treated as waste and disposed of in the regular trash.

16. Legal

**Pac-Dent Inc. releases all legal liability if the end user deviates from instructional guidance and/or using invalidated equipment that may alter the function and/or performance of the medical device.