Rodin Surgical Guide

Instructions For Use Guide

1. Material Description

Rodin Surgical Guide is a Biocompatible, Class I resin use fabricating maxillary and mandibular arch custom fitting surgical guide appliances in combination with CAD/CAM systems.

2. Composition

Rodin Surgical Guide resin is comprised of a methacrylate based resin, photo initiator, organic fillers, photo inhibitors, and pigments.

3. Intended Customer

Rodin Surgical Guide 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 licensed practitioner) unless state and local laws permit otherwise.

4. Intended Use

Rodin Surgical Guide resin use is specific for fabrication of maxillary and mandibular arch custom surgical guide appliances. Rodin Surgical Guide 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 a scanned 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.

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5. Contraindications

5.1 Patients with allergies specific to methacrylate monomers.

6. Orientation & Supporting

6.1 Orientate surgical guide appliance designs with adaptive sensitive areas facing away from the build plate and position at a 45-degree angle. Avoid placing supports within adaptive sensitive areas including drilling access holes which may prevent the guide from fully seating and adversely effecting drilling angles.

6.2 The recommended minimum support diameter at the point of contact is 0.3mm. This is where the support tip meets the designed appliance.

6.3 The recommended minimum support height is 2mm. The minimum height recommendation reduces the overall printing time, and allows for easy removal of printed appliance from the build plate.

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 or spatula to gently mix resin if it has been sitting for longer than a 12-hour period.

7.2 Before dispensing the resin from the bottle, use a plastic spatula to stir the bottom of the bottle for 1 minute minutes before dispensing or mix using an automated bottle roller for 10 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 the chemical components to mix thoroughly.

8. Post-processing Instructions

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

8.2 Wash printed surgical guides in 99% IPA in a vortex or ultrasonic bath for 5 minutes then move semi clean parts to a secondary vortex or ultrasonic bath with fresh 99% IPA for an additional 5 minutes.

Note - Do not expose bite splints to IPA for longer than 10 minutes in total to prevent material strength loss.

8.5 Use compressed air to remove excess IPA and/or residual uncured resin.

8.6 Repeat steps 4 and 5 until the restoration is thoroughly clean leaving a shine-free, matte finish.

8.7 Post-cure trays in a validated light curing device following recommended time and temperature schedules if applicable.

Note – Post curing must be performed to be in compliance with FDA.

9. Validated 3D Printers

9.1 Ackuretta Sol

10. Validated Light Curing Devices

10.1 Otoflash – Post cure at 4500 flash cycles (recommended for optimum mechanical properties).

10.2 Dreve PCU LED N2 – 30 minutes @ 80% Light intensity

10.3 Ackuretta Curie – 20min, P16, D10, BL On

10.4 Form labs Form Cure – 30 minutes @ 60C

Note - No inert or vacuum environment required when post curing.

11. Chairside Adjustments

11.1 If making chair side adjustments to surgical guide appliances, remove undesired material with standard dental carbide burs. Smooth sharp edges and remove burs with dental polishing wheels prior to inserting into the mouth.

12. Environment Conditions

12.1 3D photopolymer resins are very light-sensitive, sensitive to ambient office lights and sun light from a window. Do not leave resin bottles open. Resin that has been poured into a resin tank should be covered if not used.

12.2 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.

13. 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.

14. 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.

15. 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 restoration.