



SURGICAL GUIDE 2.0



Instruction For Use

Rodin Surgical Guide 2.0

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TABLE OF CONTENTS

1. Device Description.....	3
2. Material Composition	3
3. Intended Customer	3
4. Intended Use	3
5. Contraindications	3
6. Safety Information.....	3
7. Design Considerations.....	4
7.1. Gap Offset Adjustments	4
Increase Gap Offset:	4
Decrease Gap Offset:	4
7.2. Luting Agent Application	4
8. Validated Equipment.....	4
8.1. Validated 3D Printers	4
8.2. Validated Light-Curing Parameters	4
9. Printing Preparation	4
9.1. Mixing Recommendations	4
9.2. Mixing Resin in the Vat:.....	5
9.3. Preparing Resin from the Bottle	5
9.4. Caution with Aluminum Build Plates	5
9.5. Nesting and Orientation	5
10. Post-Processing Instructions	6
10.1. Removal from Printer	6
10.2. Removing Excess Resin	6
11. Cleaning Guides.....	6
11.1. Cleaning Recommendations: Rodin® Universal Resin Cleaner	6
11.2. Cleaning Recommendations: Isopropyl Alcohol (IPA)	7
12. Support Removal and Adjustments	8

13.	Finishing and Polishing.....	8
13.1.	Post-Curing in an Inert Environment.....	8
13.2.	Conventional Polishing Workflow.....	8
	Initial Polishing.....	8
	Intermediate Polishing.....	8
	Steam Cleaning.....	8
	Final High-Shine Polishing.....	8
14.	Printing Environment Conditions.....	9
14.1.	Light Exposure.....	9
14.2.	Resin Handling.....	9
14.3.	Temperature.....	9
15.	Storage Conditions and Shelf Life.....	9
16.	Disposal Recommendations.....	9
16.1.	Classification of Waste.....	9
16.2.	Disposal of Liquid Resin.....	10
16.3.	Solid Resin Waste.....	10
16.4.	Personal Protective Equipment (PPE) and Cleaning Material.....	10
17.	Legal Disclaimer.....	10
18.	Manufacturer Information.....	11

1. DEVICE DESCRIPTION

Rodin Surgical Guide 2.0 is a biocompatible, light-curable resin indicated for the fabrication of 3D-printed dental surgical guides used during dental implant procedures. Rodin Surgical Guide 2.0 requires a computer-aided design and manufacturing (CAD/CAM) system including an intraoral or laboratory scanner, design software, additive 3D printer, and light-curing unit. The resin is intended for use with validated 3D printers and post-curing devices according to the manufacturer's instructions.

2. MATERIAL COMPOSITION

Rodin Surgical Guide 2.0 resin is comprised of

- Methyl methacrylate resin
- Photoinitiator
- Photoinhibitor
- Pigment

3. INTENDED CUSTOMER

The product is exclusively intended for use by trained professional dentists or dental lab technicians. Sales are restricted to:

- Dental supply dealers
- Teaching institutions
- Government dental facilities

4. INTENDED USE

Rodin Surgical Guide 2.0 is intended for the fabrication of customized 3D-printed dental surgical guides used during dental implant procedures. Fabrication requires a CAD/CAM workflow and validated 3D printing and post-curing equipment.

5. CONTRAINDICATIONS

This product is contraindicated in patients with known hypersensitivity or allergic reactions to methacrylate-based resins or any of the product components. If an allergic reaction occurs, discontinue use and advise the patient to seek appropriate medical care.

6. SAFETY INFORMATION

Recommended personal protective equipment (PPE) includes:

- Gloves
- Eye protection

- Lab coat
- Closed-toed shoes

7. DESIGN CONSIDERATIONS

7.1. Gap Offset Adjustments

Increase Gap Offset:

If metal sleeves do not fit into the access channel, increase the gap offset. This adjustment is crucial to allow metal sleeves to drop in without excessive adjustment that may compromise the strength and durability during use.

Decrease Gap Offset:

If metal sleeves are loose or easily fall out of the access channel after insertion, decrease the gap offset to ensure a more secure fit.

7.2. Luting Agent Application

For optimal adherence, apply a luting agent to both the exterior of the metal sleeve and the interior walls of the access channel before inserting the sleeve.

These guidelines are essential for maintaining the effectiveness and durability of appliances created using Rodin Surgical Guide 2.0 Resin. Proper gap offset adjustments and the use of luting agents are key to ensuring the integrity and functionality of the final product.

8. VALIDATED EQUIPMENT

8.1. Validated 3D Printers

For the most current list of validated equipment and their settings, please refer to the provided link:

<https://rodin-3d.com/validated-equipment-settings/>

8.2. Validated Light-Curing Parameters

For the most current list of validated equipment and their settings, please refer to the provided link:

<https://www.rodin-3d.com/3d-printers/light-curing-devices>

9. PRINTING PREPARATION

9.1. Mixing Recommendations

Importance of Mixing: Since 3D printing resins contain chemicals of varying densities, thorough mixing is crucial. This ensures a homogeneous mixture, which is essential for consistent printing quality.

9.2. Mixing Resin in the Vat:

For resin that's already in the printer's vat:

- Use a silicon blade to gently mix the resin, particularly aiming to re-suspend any settled particles at the bottom of the tank.
- If a previous print has failed, strain the resin using a 50-micron mesh strainer to remove any debris. Metal strainers should be avoided as they can cause oxidation and alter the resin's color.

9.3. Preparing Resin from the Bottle

- Before using resin from a new bottle or one that has been sitting for a while, stir the bottom of the bottle thoroughly with a plastic spatula for several minutes.
- Alternatively, place the bottle on an automated roller for 30 minutes to ensure even mixing.
- If the resin has been stored for more than a month, roll the bottle for 1 hour. This helps ensure uniform consistency before printing.

9.4. Caution with Aluminum Build Plates

Some 3D printers have aluminum build plates that can oxidize when in contact with uncured resin. This oxidation can change the color of the resin if it's reintroduced back into the vat or original bottle. Hence, it's important to be cautious when dealing with such build plates to avoid color alterations in the printed surgical guide.

By following these mixing recommendations, users can maintain the integrity of the resin, leading to higher quality and more reliable dental guide.

9.5. Nesting and Orientation

Effective orientation is crucial in 3D printing with Rodin Surgical Guide 2.0 Resin to optimize the printing process and achieve the best possible results. Here are specific guidelines for orienting surgical guide appliances:

- Position the guide with the occlusal surface facing the build platform.
- Print in a 0° orientation to maintain dimensional accuracy and proper fit.
- Support placement should follow the validated printer settings.

10. POST-PROCESSING INSTRUCTIONS

Maximizing the quality and longevity of 3D printed surgical guides necessitates strict adherence to the post-processing instructions. Below are the key steps to be followed:

10.1. Removal from Printer

Post-Printing Removal: Gently detach the build platform from the 3D printer.

Surgical Guide Removal: Utilize a metal spatula, maintaining a perpendicular angle to the build plate, to carefully detach printed guides.

10.2. Removing Excess Resin

Resin Removal: Employ low-pressure air to dispel any uncured resin from the model and build plate.

Aluminum Build Plate Caution: Resin may discolor if in contact with an aluminum build plate due to potential contamination from grey metal oxides.

Spatula Guidance: Glide a metal spatula under the print base, encircling the perimeter until the print detaches. Ensure the spatula is parallel to the build plate for printout removal.

11. CLEANING GUIDES

11.1. Cleaning Recommendations: Rodin® Universal Resin Cleaner

1. Remove Excess Resin: Wipe away or blow off excess residual resin from the printed object using compressed air or a paper towel.

2. Run Prewash Cycle 3 Minutes:

Place the object in an ultrasonic, vortex, or oscillating bath filled with Rodin® Universal Resin Cleaner. Run the prewash cycle for 3 minutes.

3. Scrub Surface (Optional):

After the prewash, dip a clean brush into a fresh batch of Rodin® Universal Resin Cleaner and thoroughly scrub the entire surface of the object.

4. Run Secondary Wash Cycle 3 Minutes:

Transfer the object to an ultrasonic, vortex, or oscillating bath filled with fresh Rodin® Universal Resin Cleaner. Run this secondary cycle for 3 minutes.

5. Dry the Object:

Blow off any remaining wash solution using compressed air until the object is completely dry.

6. Inspect for a Matte Finish: Crucial before post-curing. Examine the object closely for any shiny spots.

- If shiny areas are present: Residual resin remains. Repeat the secondary wash (Step 4) and drying process (Step 5).
- If the surface is completely matte: The object is clean and ready for characterization or post-curing procedures.

11.2. Cleaning Recommendations: Isopropyl Alcohol (IPA)

Never submerge printed objects in Isopropyl Alcohol for a combined total of more than 10 minutes. Prolonged exposure to IPA will break down the resin, causing degradation to the mechanical properties and structural integrity of the final printed part.

1. Remove Excess Resin:

Wipe away or blow off excess residual resin from the printed object using compressed air or a paper towel.

2. Run Prewash Cycle 3-4 Minutes:

Place the object in an ultrasonic, vortex, or oscillating bath filled with IPA. Run the prewash cycle for 3 to 4 minutes.

3. Scrub Surface (Optional):

After the prewash, dip a clean brush into fresh IPA and thoroughly scrub the entire surface of the object. Do not leave the part soaking in a bath during this step.

4. Run Secondary Wash Cycle 3-4 Minutes:

Transfer the object to an ultrasonic, vortex, or oscillating bath filled with fresh IPA. Run this secondary cycle for 3 to 4 minutes.

5. Dry the Object:

Immediately after removing the part from the secondary wash, blow off all remaining solvent using compressed air until the object is completely dry.

6. Inspect for a Matte Finish: Crucial before post-curing. Examine the object closely for any shiny spots.

- If shiny areas are present: Residual resin remains. Do not run another full wash cycle. Spot-clean the shiny areas manually with a brush dipped in fresh IPA, then dry immediately with compressed air.
- If the surface is completely matte: The object is clean and ready for characterization or post-curing procedures.

12. SUPPORT REMOVAL AND ADJUSTMENTS

- Remove supports using a low-speed handpiece with a dull carbide bur.
- Perform contour and occlusal adjustments using ceramic wheels, carbide burs, or diamond burs.

Green State Adjustment:

All adjustments should be performed before final curing to prevent micro-fracturing.

13. FINISHING AND POLISHING

13.1. Post-Curing in an Inert Environment

It is recommended to post-cure printed surgical guides in an inert environment, such as nitrogen. Post-curing in an oxygen-free environment improves polymerization and enhances polishability, helping the final surgical guide maintain a high-gloss surface.

Follow the validated curing parameters listed in Section 8.2 Validated Light-Curing Parameters

13.2. Conventional Polishing Workflow

Initial Polishing

- Use a lathe with a cotton or synthetic rag wheel and 50 µm pumice under heavy pressure to smooth the surface.
- Rinse off residual pumice using a steam gun.

Intermediate Polishing

- Apply an acrylic polishing compound with light pressure.
- Add water and lightly polish to begin developing a high-shine surface.

Steam Cleaning

After using the abrasive compound, steam clean the surgical guide to remove residual polishing materials and ensure a clean surface before final polishing.

Final High-Shine Polishing

For the final polish, use a rag wheel with fine-grit diamond paste to produce a smooth, high-gloss finish.

14. PRINTING ENVIRONMENT CONDITIONS

Maintain the following environmental conditions to ensure consistent printing performance.

14.1. Light Exposure

- Protect resin from direct sunlight and UV light.
- Keep the resin covered when not in use.

14.2. Resin Handling

- Keep resin bottles tightly closed.
- Ensure the resin vat and mixing tools are clean before use.

14.3. Temperature

- Recommended printing temperature: 21–29°C (70–85°F).
- For printers with temperature control, a printing temperature of approximately 35°C may improve resin flow.
- If resin has been stored in a cold environment, allow it to reach room temperature before printing.

15. STORAGE CONDITIONS AND SHELF LIFE

- Store in the original tightly closed container in a cool, dry, and well-ventilated place.
- Recommended storage temperature: 4°C to 25°C (40°F to 75°F).
- Protect from direct sunlight, UV light, curing light sources, excessive heat, moisture, contamination, and ignition sources.
- Do not freeze.
- Keep the container upright and tightly closed when not in use.
- Refer to product labeling for the expiration date. Do not use after expiration.

16. DISPOSAL RECOMMENDATIONS

16.1. Classification of Waste

Dispose of resin and resin-contaminated materials in accordance with applicable federal, state, and local regulations. Uncured resin should be

treated as chemical waste and must not be discharged into drains, sinks, or the environment.

16.2. Disposal of Liquid Resin

Do not dispose of uncured liquid resin directly into the trash or down the drain. Unused or waste resin should be fully cured using an appropriate UV light source before disposal, where permitted by applicable regulations.

16.3. Solid Resin Waste

Ensure printed models, failed prints, supports, and other resin waste are fully cured before disposal. Fully cured resin waste may be disposed of as solid waste in accordance with applicable local regulations.

16.4. Personal Protective Equipment (PPE) and Cleaning Material

Dispose of gloves and other PPE contaminated with uncured resin in accordance with applicable waste-disposal requirements. Paper towels, cloths, and other cleaning materials contaminated with uncured resin should be fully cured before disposal, where appropriate.

17. LEGAL DISCLAIMER

Pac-Dent Inc. Release of Liability

Pac-Dent Inc. (“the Company”) expressly disclaims any and all liability associated with the improper use of its products, including but not limited to its range of 3D printing resins, tools, and equipment intended for dental applications. The end user (“User”) acknowledges and agrees that strict adherence to the instructional guidance provided by the Company is essential for the correct function and performance of the medical device (“Product”).

The User understands that deviation from the provided instructional guidance, or the use of invalidated or unauthorized equipment in conjunction with the Product, may result in alterations to the function and performance of the Product. The Company shall not be held responsible or liable for any such alterations or any consequences thereof.

By using the Product, the User agrees to indemnify, defend, and hold harmless Pac-Dent Inc., its officers, directors, employees, agents, affiliates, successors, and assigns from and against any and all losses, claims, damages, expenses (including reasonable attorneys’ fees), or liabilities of any kind arising out of, related to, or in connection with the User’s deviation from the provided instructional guidance or use of invalidated equipment.

This release of liability is binding upon the User, and, as applicable, the User's heirs, executors, administrators, legal representatives, and assigns. It is the User's responsibility to ensure comprehension and observance of this disclaimer and all accompanying instructional materials provided by the Company.

THE COMPANY'S LIABILITY UNDER THIS DISCLAIMER, IF ANY, SHALL BE LIMITED TO THE PURCHASE PRICE PAID BY THE USER FOR THE PRODUCT. IN NO EVENT SHALL THE COMPANY BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, OR INDIRECT DAMAGES ARISING OUT OF OR IN CONNECTION WITH THE USE OR PERFORMANCE OF THE PRODUCT.

The User's acceptance of the Product constitutes acceptance of these terms and an agreement to be bound hereby.

18. MANUFACTURER INFORMATION



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