



RODIN®
3D Resin

A Pac-Dent Brand

FLEXISPLINT

For Digital Corrective Oral Appliances



Instruction For Use

Rodin FlexiSplint

Instructions for Use

Revision 090426

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.....	4
7. Design and Orientation Considerations	4
7.1. Gap Offset Recommendation	4
7.2. Fit Adjustment	4
7.3. Minimum Thickness	4
7.4. Orientation.....	4
8. Mixing	4
9. Cleaning Guides	5
9.1. Cleaning Recommendations: Rodin® Universal Resin Cleaner.....	5
9.2. Cleaning Recommendations: Isopropyl Alcohol (IPA)	5
10. Post-processing Instructions	6
11. Validated Equipment.....	6
11.1. Validated 3D Printers	6
11.2. Validated Light Curing Devices	6
12. Finishing Recommendations	6
12.1. Traditional Finishing Method	6
12.2. Digital Finishing Method.....	7
13. Chairside Adjustments.....	7
14. Storage Conditions and Shelf Life	7
15. Disposal Recommendations.....	7
15.1. Classification of Waste.....	7

15.2.	Disposal of Liquid Resin	7
15.3.	Solid Resin Waste.....	8
15.4.	Personal Protective Equipment (PPE) and Cleaning Materials.....	8
16.	Legal Disclaimer.....	8
17.	Manufacturer Information	9

1. DEVICE DESCRIPTION

Rodin FlexiSplint is an advanced material specifically designed for creating clear, custom full arch mouth guards, snoring correction appliances, and occlusal bite splints. Renowned for its precision and comfort, this resin is ideal for both clinical and laboratory settings. It ensures a perfect fit tailored to individual patient needs and streamlines the production workflow, enabling the expedited delivery of high-quality protective and corrective dental products.

2. MATERIAL COMPOSITION

Rodin FlexiSplint 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 FlexiSplint resin use is specific for fabrication of 3D printed corrective oral appliances. Rodin 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.

5. CONTRAINDICATIONS

Methyl Methacrylate Allergy: Patients who have a known allergy to methyl methacrylate should not be prescribed products containing this compound. Methyl methacrylate is a common ingredient in dental resins and acrylics. Exposure to materials containing it can trigger allergic reactions in sensitized individuals. These reactions can range from mild (such as skin irritation or rash) to severe (such as anaphylaxis, which is a potentially life-threatening condition).

6. SAFETY INFORMATION

Recommended personal protective equipment (PPE) includes:

- Gloves
- Eye protection
- Lab coat
- Closed-toed shoes

7. DESIGN AND ORIENTATION CONSIDERATIONS

7.1. Gap Offset Recommendation

To achieve an optimal balance between a passive and retentive fit, set the gap offset within the range of 100–150 μm .

7.2. Fit Adjustment

Increase Gap Offset: If the guard or appliance fits too tightly, causing patient discomfort or difficulty during removal, increase the gap offset to improve fit and patient comfort.

Decrease Gap Offset: If the guard or appliance is loose or prone to dislodgement after insertion, decrease the gap offset to provide a more secure fit.

7.3. Minimum Thickness

Design the guard or appliance with a minimum thickness of 1.5 mm to provide adequate durability and protection.

7.4. Orientation

Position bite splints, night guards, and corrective snoring appliances at a 15-degree incline with the intaglio surface facing away from the build plate.

8. 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.

- For resin already in the resin vat, use a silicone blade or spatula to gently mix resin if it has been sitting for longer than a 12-hour period.
- Before dispensing the resin from the bottle, agitate the bottle for 1 minute.

Printing Temperature: Maintain the resin at the recommended printing temperature for optimal viscosity and print performance. Where applicable, a printing temperature of approximately 30°C is recommended. If the resin is cold prior to printing, allow it to reach the recommended printing temperature before use.

9. CLEANING GUIDES

9.1. 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.

9.2. 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.

10. POST-PROCESSING INSTRUCTIONS

1. After completion of the print job, remove the build platform from the 3D printer.
2. Carefully remove the printed appliance from the build platform.
3. Clean the printed appliance according to the applicable cleaning procedure in Section 9.
4. Ensure the printed appliance is completely clean and dry before post-curing.
5. Post-cure using a validated light-curing device and the applicable validated curing parameters.

11. VALIDATED EQUIPMENT

11.1. Validated 3D Printers

Please click on the link below for up-to-date information on validated 3D printers.

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

11.2. Validated Light Curing Devices

For optimal post-curing of 3D printed appliances, use only validated light-curing devices and settings. The most current list of validated equipment and corresponding cure parameters is available at:

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

12. FINISHING RECOMMENDATIONS

12.1. Traditional Finishing Method

For guards or appliances fabricated with Rodin FlexiSplint Resin, post-cure the appliance using an inert gas prior to polishing. Post-curing in an inert environment improves surface polymerization, facilitates polishing, and helps maintain a high-shine finish.

12.2. Digital Finishing Method

Apply a thin layer of Rodin FlexiSplint resin to the printed guard or appliance prior to final curing where this finishing technique is used. Light-cure the appliance in combination with an inert gas to fully cure the coated surface.

13. CHAIRSIDE ADJUSTMENTS

If chairside adjustment of the printed guard or appliance is necessary, remove undesired material using appropriate dental carbide burs. Smooth any sharp edges and finish the adjusted areas using appropriate dental polishing instruments.

14. 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.
- If resin is transferred from the vat for storage, filter it through a fine non-metallic mesh strainer and store it in a separate clean, light-protected container.
- Do not return used resin to the original container.
- Refer to product labeling for the expiration date. Do not use after expiration.

15. DISPOSAL RECOMMENDATIONS

15.1. 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.

15.2. 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.

15.3. 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.

15.4. Personal Protective Equipment (PPE) and Cleaning Materials

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.

16. 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.

17. MANUFACTURER INFORMATION



Pac-Dent, Inc.

670 Endeavor Circle | Brea, CA 92821 | USA

+1 (909) 839-0888 | www.rodin-3d.com | www.pac-dent.com