RODIN®
3D Resin

A **Pac-Dent** Brand

BITE TRAY

Instruction For Use

Pac-Dent®
Passion for Excellence

For Custom Bite Trays

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Revision 090426

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1. DEVICE DESCRIPTION

Rodin Bite Tray resin is for use in fabricating custom full and quadrant maxillary and mandibular arch impression bite trays in combination with CAD/CAM systems.

2. MATERIAL COMPOSITION

Rodin Bite Tray 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 Bite Tray resin use is specific for fabrication of 3D printed custom bite trays. Rodin resin requires a computer-aided design and manufacturing (CAD/CAM) system including 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

Designing bite trays with a thickness below 2mm is not recommended for custom and stock tray designs. Breakage of tray and/or deformation of impression body may occur when removing tray from the patient's mouth.

Designing impression trays without retention holes may lead to set impression material separating from tray when removing from the patient's mouth.

6. ORIENTATION & SUPPORTING

Orient both upper and lower bite tray designs with adaptive tissue area side down at a 45-degree angle. Place the supports on the parameter of the ridge. Avoid placing

supports in the adaptive sensitive areas which may collide with teeth and prevent tray from seating when impression taking.

The recommended minimum support diameter is 0.3mm at the point of contact where the support meets the restoration.

The recommended minimum support height is 2mm for ease of tray removal.

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.

- 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

8. CLEANING GUIDES

8.1. 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.

8.2. 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.

9. POST-PROCESSING INSTRUCTIONS

1. After completion of the print job, remove the build platform from the 3D printer.
2. Carefully remove the printed bite tray from the build platform.
3. Clean the printed bite tray according to the applicable cleaning procedure in Section 8.

4. Ensure the printed bite tray is completely clean and dry before post-curing.
5. Post-cure using a validated light-curing device and the applicable validated curing parameters.

10. VALIDATED EQUIPMENT

10.1. 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/

10.2. Validated Light Curing Devices

For optimal post-curing of 3D printed dental restorations, 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

11. CHAIRSIDE ADJUSTMENTS AND IMPRESSION TAKING

- If making chair side adjustments to the bite tray, remove undesired material with standard dental carbide burs. Smooth sharp edges and remove burs with dental polishing wheels.
- Follow recommended manufacturer's impression kit instructions when dispensing impression material and allow impression material to fully set before tray removal from patient's mouth.

12. 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.

13. DISPOSAL RECOMMENDATIONS

13.1. 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.

13.2. 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.

13.3. 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.

13.4. 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.

14. 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.

15. MANUFACTURER INFORMATION

Pac-Dent, Inc.

670 Endeavor Circle | Brea, CA 92821 | USA

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