



RODIN[®]
3D Resin

SOFT RELINE KIT



Instruction For Use



Compatible with 3D, PMMA, and Acrylic Denture Materials!

SOFT RELINE

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Device Description

RODIN Soft Reline Material is a silicone-based solution, certified as OTC Class II material, designed to improve fit of both removable and fixed full or partial dentures. Tailored for superior bonding and tear strength, it is ideal for 3D printed polymer bases, as well as PMMA milled and traditional acrylic materials. This material is particularly beneficial for patients in need of immediate dentures following extractions, surgeries, or implant procedures. Its unique, tasteless, and odorless formula is engineered for maximum comfort and performance, ensuring patient satisfaction.

Material Composition

RODIN Soft Reline is comprised of:

- Silicone
- Silica
- Cross-linker

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 It is labeled for sales to dentists (or properly licensed practitioners) only.

Intended Use

The product is designed for relining the intaglio surfaces of different types of immediate dentures, including removable, screw-retained (All-On-X), and snap-on dentures, to improve comfort and fit. It addresses several specific needs:

- Easing discomfort from sharp alveolar bone ridges and mucous membrane atrophy.
- Enhancing denture retention in cases of significant ridge atrophy.
- Managing issues related to major undercuts or the presence of maxillary or mandibular tori.
- Supporting the retention of overdentures before final attachment.
- Serving as a temporary lining or for tissue conditioning.

Contraindications

Vinyl Polysiloxane (Silicone) and Platinum Compound Allergies: Patients who have a known allergy to silicone and Platinum compounds should not be prescribed products containing this compound. Silicone is a common component in dental soft reline materials. Exposure to this material can trigger allergic reactions in sensitive 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).

PPE Recommendations

Recommended personal protective equipment includes:

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

Precautions

1. RODIN Soft Reline is designed for sale and use by licensed dental care professionals only. It is not designed for sale nor is it suitable for use by non-dental care professionals.
2. Use RODIN Soft Reline as instructed herein. DO NOT use SP Reline S for any application other than those noted in these instructions.
3. DO NOT use RODIN Soft Reline if the safety seal is broken or if it appears the contents have been tampered with.
4. RODIN Adhesive Primer contains ethylacetate, which is a highly flammable and volatile solvent. Do not expose RODIN Adhesive Primer to open flame. Use in a ventilated room during use and close the cap tightly after use.
5. If patient experiences an allergic reaction or sensitivity to RODIN Soft Reline, such as a dermatitis outbreak, remove the prosthesis and discontinue its use immediately.
6. Wear non-latex examination gloves at all times while using RODIN Soft Reline to avoid the possibility of allergic reactions. Latex gloves may also inhibit the setting of RODIN Soft Reline. If RODIN Adhesive Primer comes in contact with the examination gloves, immediately dispose of the examination gloves and wash hands thoroughly with water.
7. Avoid contact with eyes. In case of contact with eyes, thoroughly flush eyes with water, and immediately contact a physician.
8. Avoid contact of unset chemical with skin. In case of contact with skin, clean affected area with rubbing alcohol, then thoroughly flush with water.
9. Avoid contact of unset materials with clothing. In case of contact with clothing, do not wipe the material. Allow it to set and then peel it off.
10. DO NOT allow excess materials to flow down the patient's trachea or esophagus. Aspirated or ingested RODIN Soft Reline VPS can cause asphyxiation or other injury. Immediately remove any excess lining material from the palatal area to avoid material flowing down the patient's throat.

RODIN Soft Reline VPS is not radiopaque, and radiographs will not detect aspirated or ingested material. In case of an elderly patient whose reflex ability is compromised, set the chair in an upright position and instruct the patient to breathe through the nose in order to prevent the material from entering the airway.

Surface Preparation Recommendations

Remove old soft reline material from denture base if present with RODIN VPS Release liquid.

Preparation

- 1) Check intraoral condition by inspection and palpation. Remove denture from patient's mouth and clean the area to be lined with soap and water. Rinse thoroughly and completely dry the denture surface.
- 2) Expose the acrylic surface by cutting back existing Soft Reline material 2-5 mm in width and 10-20 mm in length with a scalpel.
- 3) Soak applicator with RODIN VPS Release liquid.
- 4) Dampen the exposed area using the soaked applicator and allow it to sit for 5-10 seconds.
- 5) Remove all remaining silicone reline material by pulling away from the denture. Apply more RODIN VPS Release as needed.

Prepare the intaglio and flange surfaces of the denture

- 1) Bevel the borders of the denture using the tapered green stone bur.
- 2) Use a brown scotch bright wheel, scour the intaglio surfaces including the beveled area where Adhesive Primer will be applied.
- 3) Rinse or steam clean treated surface removing all residual debris.
- 4) Completely dry the treated surface with compressed air.

Application of RODIN Adhesive Primer and Soft VPS Silicone

- 1) Using the included applicator swab, apply a thin, even layer of RODIN Adhesive Primer to the areas of the denture that require relining. Allow the RODIN VPS Adhesive Primer to dry for at least 2 minutes before applying the VPS silicone to the treated area.
- 2) Insert RODIN Dual cure silicone cartridge on to a dual barrel cartridge gun and remove the cap.
- 3) Insert a new mixing tip onto the cartridge.
- 4) Discard the initial amount of silicone upon first use for a consistent mix.
- 5) Apply the Soft Reline silicone evenly across treated surfaces where Adhesive Primer was applied using the mixing tip or a spatula. Recommended working time is 90 seconds.

*Note** To prevent contamination, do not remove used mixing tip on the dual barrel silicone cartridge until ready for next use.*

- 6) Immediately place relined denture into patient's mouth and allow patient to close bite for best occlusion. Have patient continue resting bite for 5 minutes to allow silicone to completely set prior to removing denture to trim away excess silicone.

- 7) Remove the relined denture from the mouth. Carefully trim excess material with a sharp scalpel.
- 8) Use Coarse Point to smooth beveled surfaces and adjust the shape, as needed.
- 9) Use the scotch bright Brown Wheel to finish the beveled areas.
- 10) Rinse or steam off residual debris.
- 11) Deliver relined denture to patient.

Patient Care Instructions

To maintain optimal performance, soak the dentures overnight in a denture cleaning solution.

*Note** Avoid using abrasive tooth-whitening pastes on the treated surface, as they can weaken the bond between the soft reline material and the denture.*

Recommended Storage

To ensure optimal performance, store RODIN Soft Reline products in a dark, cool, dry area.

1. Store in a temperature range between 0 - 25°C (32 - 77°F).
2. Avoid direct exposure of Rodin Soft Reline to heat, open flame, humidity, and sunlight.
3. Do not use RODIN Soft Reline after the indicated date of expiration.

Recommended Shelf Life

The shelf life of Rodin Soft Reline is 3 years.

Disposal Recommendations

CLASSIFICATION OF WASTE Regulatory Compliance: Familiarize yourself with and comply with all applicable federal, state, and local regulations concerning hazardous waste disposal.

Hazardous Waste Identification: Consult the US EPA guidelines and other relevant sources to accurately classify whether the waste you're disposing of is considered hazardous.

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.



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