



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:

- Removable dentures
- Screw-retained dentures (All-On-X)
- Snap-on dentures

This application ensures enhanced comfort and fit for various denture types.

Contraindications

Vinyl Polysiloxane (Silicone) Allergies: Patients who have a known allergy to silicone 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

Surface Preparation Recommendations

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

- 1) 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.
- 2) Soak applicator with RODIN VPS Release liquid.
- 3) Dampen the exposed area using the soaked applicator and allow it to sit for 5-10 seconds.
- 4) 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) Dry the treated surface.

Application of RODIN Soft Reline Product

- 1) Apply a thin even coat RODIN Adhesive Primer to the denture lining and beveled areas using the provided applicator swab. Allow RODIN VPS Adhesive Primer a minimum of 2 minutes to dry before applying silicone to the treated surface.
- 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.
- 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 toothpastes 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.

Recommended Shelf Life

The products have a shelf life of 18 months.

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.

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.

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.

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



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