

INSTRUCTIONS FOR USE

Dura Rely-A-Soft

Denture Liner

DESCRIPTION:

Denture Reliner is specifically formulated to provide comfort, durability, and compatibility with oral tissues. This device contains a composition of powder reagents (2-Propenoic acid, 2-methyl-Ethyl ester, homopolymer, Benzoyl peroxide and Titanium Dioxide) and liquid reagent (Triphenyl Phosphate) to reline a denture in a specified mixing ratio. The materials are carefully selected and formulated to ensure biocompatibility with the oral tissues and durability for daily use. It is available in various kit sizes. The relined denture can be worn daily for up to six months. The device is supplied as Non-Sterile.

INTENDED PURPOSE:

The intended purpose of the material is to reline full or partial dentures that enhance the fit, comfort, and stability of removable dentures by providing cushioning, improving fit, and reducing pressure points on the gums.

INDICATION FOR USE:

- Constant friction between poorly fitting dentures and gums can lead to sore spots, irritation, and even the development of ulcers.
- Immediate Dentures, in this case denture reliner are used to reline denture according to patient's oral anatomy.
- Stabilizing Loose Dentures.
- Aging Dentures.
- Difficulty in Chewing or Speaking.
- Denture Repairs.
- Improved Comfort.

INTENDED PATIENT POPULATION:

Intended to use in patients above 25 years of age.

INTENDED USER POPULATION:

The device is intended to be used by dentists in the laboratories to reline a non-fitting denture for the patient.

EXPECTED CLINICAL BENEFITS:

- Improved the Quality of life, satisfaction, self-confidence and contentment of the patients.
- Pain reduction
- Recovery from masticatory ability (MA)
- Reduces the residual ridge resorption.

PERFORMANCE CHARACTERISTICS:

- Uniform stress distribution
- Improve stability of the dentures
- Improvement of retention of dentures

CONTRAINDICATIONS:

- Do not use it in contact with damaged mucosa membrane.
- The device should not be used in patients with Ongoing Dental Infection.
- The device should not be used in patients with hypersensitivity or allergy to materials.

LIMITATIONS:

- Material should be handled only by trained healthcare professionals.
- Off-Labelled material should not be used.
- Not to be used as replacement for new dentures
- Not suitable for metal-based dentures.
- Not suitable for dentures that are extremely damaged.

MODE OF ACTION:

The mode of action of the device involves when a liquid reagent is mixed with a powder of small polymer beads in a specified mixing ratio, the mixture undergoes polymerization through chemical & thermal water curing activation. The polymerized resin is composed of numerous polymer units linked together to form a long-chain polymer. The polymerized resin is molded to reline a denture.

WARNING

- Store at room temperature away from direct sunlight.
- The materials are not supposed to be used beyond their shelf life for relining the denture.
Do not smoke in the presence of open containers.
- If there is any discoloration or change in the performance of the denture or discomfort is experienced while using it, notify the dentist.
- Do not use the material for a purpose other than relining the denture.
- Dispose of material in accordance with local, state, and country laws.

PRECAUTIONS:

- Consider the patient's medical history, allergies, and individual factors that may affect the choice and use of materials.
- Avoid contact with skin, eyes, and clothing.
- Wash hands thoroughly after handling.
- Wear protective gloves and safety glasses with side shields or chemical splash goggles.

- Avoid prolonged breathing of vapors and powder.
- Use with adequate ventilation.
- Rinse relined denture under warm tap water before inserting it into the mouth.
- Don't soak denture for more than 10 minutes in cleaning solution, and only use a soft bristle brush while cleaning the denture.
- Surrounding gingival tissues should be protected from the material
- Exposed vital dentin should also be protected from the material

RESIDUAL RISKS/ UNDESIRABLE SIDE EFFECTS:

May cause irritation or allergies to skin or mucous membranes due to residual monomers.

WARRANTY:

The manufacturer warrants this product to be free from manufacturing defects for four years from date of manufacture. Warranty is void if product is not used for intended purpose, not used as instructed, or not stored in the original container.

DISPOSAL:

Dispose of material in accordance with local, state, and federal regulations. When scrapped, the powder is not considered hazardous. Discarded liquid is a hazardous waste by the EPA under RCRA. It is the responsibility of the generator to determine at the time of disposal whether the product meets the criteria of a hazardous waste.

STORAGE CONDITIONS:

Close bottles tightly after use. Store in original container in a dry, well-ventilated location, away from sources of ignition and light, at room temperature.

SUPPLY:

This IFU is applicable for the following Packages

1701 - Dura Rely-A-Soft package (112g powder/120mL liquid/mixing items)

1701C - Dura Rely-A-Soft package (112g powder/120mL liquid/mixing items)

ATTENTION:

In order to avoid uncontrollable chemical reactions and contaminations, please use only mixing jars/dappen dishes and spatulas/brushes which do not get in contact with other resins.

INSTRUCTIONS FOR USE:

CHAIRSIDE TECHNIQUE:

1. Clean and roughen denture area to be rebased. Dry denture completely.
2. Lubricate the labial and buccal surfaces within 1/8" of the peripheral border.
3. Recommended powder/liquid proportions: Powder-8mL-large plastic vial, Liquid-5mL-small plastic vial. Add powder to liquid in mixing cup and stir slowly and thoroughly for approximately 15 seconds. Let mixture stand 1 minute.
4. Apply mixture to denture.
5. Insert denture in the mouth and have patient close mouth lightly into occlusion, muscle-trim the borders, then remove the denture.
6. Place the denture, reline side up, into a container filled with hot water (130°-160° F / 55°-71° C), and cure for 10 minutes. For best cure, place in a pressure pot in hot water.
7. After curing, place denture in cold water to temporarily harden the soft liner for easy trimming.
8. Remove excess flash with sharp blade or scissors. An acrylic bur can be used to taper the materials onto the labial and buccal surfaces, rinse, then place the denture in patient's mouth.

LABORATORY TECHNIQUE:

PREPARATION

1. Pour a stone model of reline impression. Flask or jig the model with impression in , place, following standard reline preferences.
2. After flask has stood for one hour, place flask in boil out tank for 15 minutes. Remove and separate upper and lower portions.
3. Clean lower half of flask with a mild detergent, flooded with a hot water rinse. Apply separator and allow to dry.
4. Relieve the denture base tissue-bearing surface by approximately 2 mm to accommodate the soft liner. Soft liner can extend above peripheral roll.
5. Roughen area of denture base to be relined and eliminate any severe undercuts.
6. Repeat cleansing of upper half of the flask and rinse with hot water, apply separator and let dry.

APPLICATION AND CURING

7. Recommended powder/liquid proportions: Powder-8mL large plastic vial, Liquid 5mL small plastic vial. (If softer liner is desired, more liquid can be added to the mixture. If firmer liner is desired, more powder can be added to the mixture.) Add powder to liquid in mixing cup and stir slowly and thoroughly for approximately 15 seconds. Let mixture stand 1 minute.

8. Apply and spread mixture onto the dry denture base surface. Close the flask or jig for curing. If jig is used, apply fingertip coated with the mixing liquid to taper and smooth excess material onto labial and buccal surfaces.
9. When curing, if a flask is being used, do not trial pack the soft liner. Slowly, close the flask completely by applying pressure, and place in a curing unit filled with boiling water (212°F/100°C) for at least 20 minutes.
10. If using a jig, put jig into a curing unit with hot water (130°-160°F/55°-71°C) for 15 minutes.
11. After curing, place denture in cold water to temporarily harden the soft liner for easy trimming.
12. Remove excess flash with sharp blade or scissors. An acrylic bur can be used to taper the liner onto the labial and buccal surfaces, then completely dry the liner.

PATIENT CARE

Only use soft bristle brush when cleaning denture.

Soak denture for no more than 10 minutes in cleaning solution.

BASIC UDI-DI: ++D94717013Y, ++D9471701CLW

REPORTING:

In case of any adverse events related to the device, it must be reported to the manufacturer & Competent Authority.

COMPETENT AUTHORITY DETAILS:

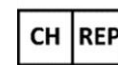
DE/CA37, Regierungspräsidium Stuttgart

Address: Ruppmannstraße, 21, Stuttgart, Germany

Email: abteilung9@rps.bwl.de

EXPLANATION OF SYMBOLS	
Symbol	Title
	CE Logo with Notified Body Number
	Manufacturer
	Swiss Authorised Representative
	Authorized Representative in the European Community/ European Union

	Date of Manufacture
	Batch code
	Use-by Date
	Catalogue Number
	Caution
	Keep away from Sunlight
	Unique Device Identifier
	Upper limit of temperature
	Medical device
	Consult instructions for use or consult electronic instructions for use
	Importer
	Distributor
	Keep dry
	Country of Manufacture



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