

Lynal®

DENTSPLY
CAULK

TISSUE CONDITIONER AND TEMPORARY RELINER

DIRECTIONS FOR USE

For dental use only.

USA: Rx only.

1. PRODUCT DESCRIPTION

Lynal® Tissue Conditioner and Temporary Reliner is a self-curing, resilient methacrylate formulation, intended for use as a limited-term soft lining material for complete and partial dentures.

1.1 Delivery forms

Lynal® Tissue Conditioner and Temporary Reliner is available in:
Powder and liquid for hand mixing
Liquid separator

1.2 Composition

Polyethylmethacrylate
Ethyl Alcohol
Citrate Ester Plasticizer
Separator: Mineral oil, spearmint oil

1.3 Indications

1. Tissue Conditioner and temporary reliner when denture-bearing soft tissues have been distorted by trauma or infection.
2. Functional impression material when a complete denture is to be rebased or remade.
3. Soft liner, especially for aged patients or patients with impaired tissue health.

1.4 Contraindications

Lynal® Tissue Conditioner and Temporary Reliner is contraindicated for use with patients who have a history of severe allergic reaction to methacrylate resins.

2. GENERAL SAFETY NOTES

Be aware of the following general safety notes and the special safety notes in other chapter of these directions for use.

2.1 Warnings

1. Lynal® Tissue Conditioner and Temporary Reliner contains polyethylmethacrylate and ethyl alcohol which may be irritating to skin and eyes and may cause allergic contact dermatitis in susceptible persons. Do not breathe vapors. Use only in well ventilated areas.

Avoid eye contact to prevent irritation and possible corneal damage. In case of contact with eyes, rinse immediately with plenty of water and seek medical attention.

Avoid skin contact to prevent irritation and possible allergic response. In case of contact, reddish rashes may be seen on the skin. If contact with skin occurs, immediately remove material with cotton and wash thoroughly with water and soap. In case of skin sensitisation or rash, discontinue use and seek medical attention.

Avoid ingestion/swallowing of material to prevent irritation or obstruction. If accidental swallowing occurs, drink lots of water. This material is not hazardous when small quantities are ingested. Larger quantities may cause bowel obstruction. Seek medical attention in the event of digestive irregularities.

2. **Danger: Extremely flammable.** Lynal® Tissue Conditioner and Temporary Reliner liquid contains Ethyl Alcohol. Use only in well ventilated areas. Keep away from heat, sparks and open flame.

2.2 Precautions

1. This product is intended to be used only as specifically outlined in the Directions for Use. Any use of this product inconsistent with the Directions for Use is at the discretion and sole responsibility of the practitioner.
2. Wear suitable protective eyewear, mask, clothing and gloves. Protective eyewear is recommended for patients.
3. The Lynal® Tissue Conditioner and Temporary Reliner containers should be tightly closed immediately after use. Replace original cap tightly after each use.
4. Lynal® Tissue Conditioner and Temporary Reliner should be used with properly fitted dentures. To reduce gagging, choking or swallowing, do not overfill dentures.
5. Interactions
 - Lynal® Tissue Conditioner and Temporary Reliner will adhere to most denture base materials and resin denture teeth. Use Lynal® Tissue Conditioner and Temporary Reliner Separator on areas where adhesion of material is not desired.
 - Eugenol containing materials should not be used in conjunction with this product because they may interfere with hardening and cause softening of the polymeric components of the material.

2.3 Adverse Reactions

- Eye contact: irritation and possible corneal damage.
- Skin contact: irritation or possible allergic response. Reddish rashes may be seen on the skin.
- Inhalation of vapors: varying degrees of damage to the affected tissue and also increased susceptibility to respiratory illness.
- Bowel obstruction or other digestive distress may result from ingestion of mixed material. (See Warnings)

2.4 Storage

Lynal® Tissue Conditioner and Temporary Reliner should be kept out of direct sunlight and stored in a well ventilated place at temperatures between 10-24°C/50-75°F. Allow material to reach room temperature prior to use. Protect from moisture. Do not freeze. Do not use after expiration date.

3. STEP-BY-STEP INSTRUCTIONS

3.1 Tissue conditioning

1. Clean denture with brush and detergent solution. Disinfect denture according to manufacturer's or dental laboratory's instructions. Relieve pressure areas and undercuts by grinding. Thoroughly rinse and dry denture surface.
2. Using the brush-cap, apply Separator for Lynal® Tissue Conditioner and Temporary Reliner only to areas where bonding is not desired e.g., external denture base and denture tooth surfaces. Do not use brush on contaminated (non-disinfected) denture surfaces.
3. Measure 10mL of powder in measuring vial. Using pipette, dispense 4.0mL of liquid into mix cup. Replace container caps. Add powder to liquid and stir for 30 seconds. Recommended powder/liquid ratio is 3g/2mL. A slight increase in the amount of powder used will produce a stiffer mix. Up to 0.5mL liquid may be added to produce a thinner mix if desired.
4. Cover tissue surface of denture with Lynal® Tissue Conditioner and Temporary Reliner mixture. To overcome the initial tackiness of the mix during placement in the denture, the operator may moisten his fingers.
5. Insert denture with Lynal® Tissue Conditioner and Temporary Reliner material into mouth approximately 2 or 3 minutes from start of mix. Remove undesired excess beyond denture, e.g., retromolar areas. Instruct patient to close gently in normal occlusion and remain in rest position for a minimum of 2 minutes. Then have the patient read aloud and perform functional movements. Alternatively, the operator can perform border molding manipulation as per usual techniques. These exercises should take approximately 2 minutes.
6. Remove denture from mouth in approximately 7 to 8 minutes from start of mix. Check for proper coverage, especially in border areas. Trim excess with a sharp instrument.
7. Recall patient after a few days. Following the above directions, a new mix may be added to deficient areas. Continue treatment until tissues have returned to normal. Technique Tip: Study models may be used to record progress of conditioning procedure. Pour cast immediately to preserve maximum detail.
8. Following completion of tissue conditioning, proceed to Functional Impression (Section 2), Soft Lining (Section 3) or standard rebasing or remaking impression techniques.

3.2 Functional impression-taking

1. The general directions above in Steps 3.1.,1-6 should be followed.
2. The application may remain in the mouth for as little as 1 hour, but no longer than 24-48 hours. Longer periods may produce distorted impressions.
3. Pour cast directly into impression without the Separator. Prepare rebase or new denture in the usual manner.

3.3 Temporary soft lining

1. The general directions above in Steps 3.1.,1-6 should be followed. Lynal® Tissue Conditioner and Temporary Reliner will act as a soft liner for varying periods of time.
2. Periodically recall patient and evaluate liner.
3. Lynal® Tissue Conditioner and Temporary Reliner should be completely removed by grinding with an acrylic bur, and replaced as outlined above, when any of the following occur:
 - Material loses resilience
 - Material exhibits surface discoloration
 - Material causes patient discomfort

3.4 Maintenance of Lynal® Tissue Conditioner and Temporary Reliner treated dentures

After 1 day in the mouth Lynal® Tissue Conditioner and Temporary Reliner treated dentures can be cleaned by gentle brushing with a soft-bristled brush and clear water. Do not use commercially available chemical cleansers. Do not immerse denture in cleaning solutions.

4. HYGIENE

4.1 Cleaning and disinfection instructions

Use of protective barriers is recommended to avoid package contamination. Repeated disinfection may cause damage to the labels.

Do not attempt to clean or disinfect Separator applicator brush stem or bristles. If brush stem or bristles become contaminated, resealing bottle without contamination of contents will not be possible. Properly dispose of brush, bottle and material.

5. LOT NUMBER AND EXPIRATION DATE

1. Do not use after expiration date. ISO standard uses: "YYYY/MM."
2. The following numbers should be quoted in all correspondences:
 - Reorder number
 - Lot number on package
 - Expiration date

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