

# Lynal<sup>®</sup>

## Tissue Conditioner & 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/plasticized acrylic formulation intended for use as a soft lining material for short-term use in removable dentures. Lynal Tissue Conditioner and Temporary Reliner is classified as and complies with ISO 10139-1, short-term Type B, class 2.

##### 1.1 Delivery forms

Lynal Tissue Conditioner and Temporary Reliner is available in:  
Powder - 120g bottle  
Liquid - 90mL bottle for hand mixing  
Liquid Separator - 15mL bottle with integrated brush cap

##### 1.2 Composition

Powder: Polyethylmethacrylate, Aspartame  
Liquid: Ethyl Alcohol, Citrate ester plasticizer, Spearmint oil flavoring  
Liquid 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.



#### Safety alert symbol

This is the safety alert symbol. It is used to alert you to potential personal injury hazards. Obey all safety messages that follow this symbol to avoid possible injury.

#### 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.
3. Lynal Tissue Conditioner and Temporary Reliner powder contains aspartame and should not be used with patients who have a history of phenylalanine metabolic disorder. In the event of exposure, PKU patients that are or may be pregnant should seek medical advice.

#### 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. To prevent the containers from exposure to spatter or spray of body fluids or contaminated hands it is mandatory that the containers are handled with clean/disinfected gloves. As additional precautionary measure, containers may be protected from gross contamination but not from all contamination by applying a protective barrier.
4. The Lynal Tissue Conditioner and Temporary Reliner containers should be tightly closed immediately after use. Replace original cap tightly after each use.
5. Lynal Tissue Conditioner and Temporary Reliner should be used with properly fitted dentures. To reduce gagging, choking or swallowing, do not overfill dentures.
6. All products should be used at room temperature. Higher temperatures reduce work times and laboratory bench set times (faster), lower temperatures increase them (slower).

#### 7. 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.
- Product contains aspartame, and may cause hyperphenylalaninemia in susceptible individuals. Hyperphenylalaninemia may have harmful effects on developing fetus. (See Warnings)
- 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. Allow materials to reach room temperature before use. At room temperature, 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 section 3.2 Functional Impression, section 3.3 Soft Lining, 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 section 3.1 steps 1-6 should be followed. Lynal Tissue Conditioner and Temporary Reliner will act as a soft liner for varying periods of time, up to 28 days.
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

1. Immediately following application and trimming, prior to delivery to the patient, dentures should be cleaned by rinsing in a gentle stream of clear water. Lined denture may be disinfected with an intermediate-level, tuberculocidal surface disinfectant according to disinfectant manufacturer's instructions. Immersion in disinfectant solutions is not recommended.
2. 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.

### Instructions for Disinfecting Product containers, measures, mixing cups and spatula

Warnings	<ul style="list-style-type: none"><li>• Intermediate level disinfection is appropriate for the Product containers, measures, mixing cups and spatula. It is not recommended to submerge product containers into disinfection solutions. Product contamination may occur. It is not recommended to submerge measures, mixing cup or spatula into disinfection solutions. Discoloration and deterioration may occur. Do not autoclave Product containers, measures, mixing cups and spatula. Vigorous wiping of containers can destroy the label. Wipe containers gently.</li></ul>
Limitations on Reprocessing	<ul style="list-style-type: none"><li>• Repeated processing has minimal effect on the Product containers, measures, mixing cups and spatula. The Product containers, measures, mixing cups and spatula can be subjected to the cleaning and disinfection process until containers are empty or material has expired, and which time materials should be properly discarded and replaced. Cold liquid disinfection/sterilization, chemical vapor sterilization, and dry heat sterilization methods have not been tested or validated for efficacy and are not recommended for use.</li></ul>
Point of Use	<ul style="list-style-type: none"><li>• Remove excess soil with disposable cloth / paper wipe. Prior to Cleaning and Disinfection, replace original caps on containers. Remove excess material with a soft paper tissue and alcohol of 70%. It is recommended that the Product containers, measures, mixing cups and spatula be reprocessed as soon as is reasonably practical following use.</li></ul>
Containment and Transportation	<ul style="list-style-type: none"><li>• No particular requirements.</li></ul>
Cleaning and Disinfection: Automated	<ul style="list-style-type: none"><li>• Methods have not been tested or validated for efficacy and are not recommended for use.</li></ul>
Cleaning and Disinfection: Manual	<ul style="list-style-type: none"><li>• The Product containers, measures, mixing cups and spatula have to be cleaned by scrubbing with hot water and soap or detergent. The product containers must be cleaned with a single-use cloth soaked in hot water and detergent. After cleaning thoroughly wipe all device surfaces with a single-use cloth in combination with a water-based, bactericidal, virucidal and fungicidal disinfection solution approved according to local regulations and use according to disinfectant solution manufacturer's Instructions for Use. Make sure disinfectant solution is compatible with cleaning solution. Pay special attention to device seams and insertions. Use of phenolic-, iodophor- or organic solvent (e.g. alcohol) based or containing products may over time cause surface staining. Remove disinfectant solution residue with a cloth soaked with water. Dry device with a lint-free single-use cloth.</li></ul>
Packaging	<ul style="list-style-type: none"><li>• No particular requirements.</li></ul>
Sterilization	<ul style="list-style-type: none"><li>• Methods have not been tested or validated for efficacy and are not recommended for use.</li></ul>
Drying	<ul style="list-style-type: none"><li>• Allow the Product containers, measures, mixing cups and spatula to fully dry before storage.</li></ul>
Maintenance	<ul style="list-style-type: none"><li>• If the Product containers, measures, mixing cups or spatula are discolored, damaged, worn, or distorted they should be discarded. No additional maintenance or lubrication is recommended.</li></ul>
Storage	<ul style="list-style-type: none"><li>• Store the Product containers, measures, mixing cups and spatula at room temperature, away from moisture or excessive humidity. Product containers, measures, mixing cups and spatula should be disinfected and dried prior to storage.</li></ul>
Manufacturer Contact	<ul style="list-style-type: none"><li>• Within the United States, call DENTSPLY at 1-302-422-4511. For areas outside the United States, contact your local DENTSPLY representative.</li></ul>

## 4. HYGIENE



### Cross-contamination - Infection

- Do not reuse single use products. Dispose of in accordance with local regulations.
- Reprocess reusable products as described below.

### 4.1 Cleaning and disinfection instructions

- To prevent containers from exposure to spatter or spray of body fluids or contaminated hands, or oral tissues, use of a protective barrier is recommended to avoid package contamination. The use of protective barriers is an additional precautionary measure against gross contamination but not against all contamination.
- For manual cleaning: Use a new clean pair of examination gloves. Discard gloves according to local regulations and disinfect hands with an appropriate bactericidal, virucidal, and fungicidal hand disinfectant solution according to local regulations. Use according to disinfectant solution manufacturer's Instructions for Use.



### Cross-contamination - Infection

- Applicator brush cannot be reprocessed. Dispose of contaminated bottle in accordance with local regulations.

Do not attempt to clean or disinfect Liquid 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



©2016 DENTSPLY International  
All rights reserved.  
Manufactured by  
Dentsply Caulk  
38 West Clarke Avenue  
Milford, DE 19963 USA  
Made in USA  
1-302-422-4511  
www.dentsplysirona.com

Distributed by:  
DENTSPLY Canada  
161 Vinyl Court  
Woodbridge, Ontario  
L4L 4A3 Canada

**553011** (R 8/9/17)