Lynal 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/polyacrylic 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 10339-1, short-term Type B Class 2.

1.1 Delivery forms
Lynal Tissue Conditioner and Temporary Reliner is available in:
Powder – 100g bottle
Liquid – 30mL 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 ingestion/swallowing of material to prevent irritation or other injury hazards. Obey all safety messages that follow this symbol to avoid possible injury.
• Avoid eye contact to prevent irritation or possible corneal damage. Wet disposable gloves
2. Lynal Tissue Conditioner and Temporary Reliner liquid contains Ethyl Alcohol. Use only in well ventilated areas. Keep away from heat, sparks and open flames.
• Avoid skin contact to prevent irritation and possible allergic response. Reddish rash may be seen on the skin. 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 with skin, 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.
• Excessive powder 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.
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.

2.2 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 clear/disinfected gloves. As additional precautionary measure, containers may be protected from gross contamination but not from all contamination of the polymeric components of the material.
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).

3. STEP-BY-STEP INSTRUCTIONS
3.1 Tissue Conditioning
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.

3.2 Application
2. Using the brush-cap, apply Separator for Lynal Tissue Conditioner and Temporary Reliner 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.

3.3 Temporary Soft Lining
1. The general directions above in section 3.1 steps 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 relase or new denture in the usual manner.

3.4 Temporary Soft Lining
1. The general directions above in section 3.1 steps 1-6 should be followed.
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

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. A. 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 spatulas

Warnings
- 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 spatulas. Vigorous wiping of containers can destroy the label. Wipe containers gently.

Limitations on Reprocessing
- 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.

Cleaning and Disinfection: Manual
- 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- or 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.

Cleaning and Disinfection: Automated
- Methods have not been tested or validated for efficacy and are not recommended for use.

Point of Use
- 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.

Maintenance
- 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.

Storage
- 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.

Manufacturer Contact
- Within the United States, call DENTSPLY at 1-302-422-4511. For areas outside the United States, contact your local DENTSPLY representative.