Sealer: Contains: Methyl Ethyl Ketone/Danger/Highly flammable liquid and vapour./Causes serious eye irritation./May cause drowsiness or dizziness./Keep away from heat, sparks, open flames, and hot surfaces. No smoking./Keep container tightly closed./Avoid breathing mist, vapors, or spray./Wash thoroughly after handling./Use only

outdoors or in a well-ventilated area./Wear protective gloves, eye protection and face protection./IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower./IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing./If eye irritation persists: Get medical attention./IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing./Call a POISON CENTER or doctor if you feel unwell./In case of fire: Use carbon dioxide, alcohol foam or dry chemical to extinguish./ Store in a well-ventilated place. Keep cool./Store locked up./Dispose of contents and container in accordance with local and national regulations.



Liquid: Contains: Dibutyl Phthalate/Danger/Flammable Liquid and vapor./Causes serious eye irritation./May damage the unborn child. Suspected of damaging fertility./Very toxic to aquatic life./Obtain special instructions before use./Do not handle until all safety precautions have been read and understood./Keep away from heat, sparks, open flames, and hot surfaces. No smoking./Keep container tightly closed./Wash thoroughly after handling./Wear protective gloves, eye protection and face protection./IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water./IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing./If eye irritation persists: Get medical attention./IF exposed or concerned: Get medical attention./In case of fire: Use carbon dioxide, alcohol foam or dry chemical to extinguish./Avoid relase to the environment./ Collect spillage./Store in a well-ventilated place. Keep cool./Store locked up./Dispose of contents and container in accordance with local and national regulations.



AUSTENAL® PermaSoft ® Soft Denture Liner

DIRECTIONS FOR USE

Laboratory Technique Chairside Technique





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Indications for Use:

PermaSoft® Soft Denture Liner is a two component system comprised by blending a powder component of polyethylmethacrylate and a liquid component of Di-n-butyl phthalate, ethyl acetate and ethyl alcohol. It is indicated for use in stabilizing and relining complete and partial dentures, cushioning sensitive tissues and retaining overdentures. Permasoft can be processed using direct or indirect techniques. The compliance and resiliency of Permasoft can be varied by altering the powder/liquid ratio.

Contraindications:

None known.

Warnings:

PermaSoft Soft Denture Liner contains methacrylate resins which may cause skin sensitization (allergic contact dermatitis) or other allergic reactions in susceptible persons. If skin sensitization occurs, discontinue use. If dermatitis or other symptoms persist, seek medical attention. PermaSoft liquid contains ethyl alcohol and should be kept away from sources of ignition. Avoid contact with eyes. In case of accidental contact, wash thoroughly with water and seek medical attention.

Keep containers tightly closed when not in use.

Precautions:

Work in a well ventilated area when applying PermaSoft Sealer and DO NOT place prosthesis in patient's mouth until PermaSoft Sealer is completely dry and prosthesis has been rinsed with water.

It's longevity of service is reduced when used as a long-term soft liner against sharp, knife edge ridges. It can be used for application over knife like ridges, but use a powder/liquid ratio of 3:1 for more resistance to hairline cracking. Adhesion of PermaSoft to each and every denture base resin formulation has not been tested. Carefully evaluate adhesion of PermaSoft to denture base formulations which do not contain polymethylmethacrylate.

Adverse Reactions:

Allergic contact dermatitis and other allergic reactions may occur in susceptible individuals.

STEP BY STEP INSTRUCTIONS

The compliance and resiliency of PermaSoft Soft Denture Liner can be varied by altering the powder/liquid ratio. PermaSoft mixed using a powder/liquid (vol/vol) ratio of 2:1 results in a very compliant lining layer suitable for postsurgical prosthetics or as a cushion against sensitive tissues. PermaSoft mixed using a powder/liquid ratio of $2\sqrt{2}$:1 results in a firmer lining which effectively stabilizes partial and complete dentures while still providing the advantages of a soft-liner for long-term use. PermaSoft mixed using a powderliquid ratio of 3:1 results in a lining capable of retaining overdentures onto natural teeth, ball abutments or bar connectors. PermaSoft forms a durable bond with conventional methacrylate resin denture base formulations.

LABORATORY TECHNIQUE

Density	Ratio (P:L)	Powder	Liquid	Applications
Softest	2:1	8cc	4cc	Post-surgical prostheticsCushion for sensitive tissue
Standard Lining	2.5:1	10cc	4cc	•Complete denture relines •Partial denture stabilization •Overdenture retained on healing caps
Firm	3:1	12cc	4cc	•Overdenture retained by ball abutments, bar connectors or teeth.

Preparation:

- Upon receipt of reline impression, pour a stone model. Flask or jig the model with the impression in place following standard reline procedures.
- After the flask has set for one hour, place it in a boilout tank for approximately 15 minutes. Remove it and separate the upper and lower portions of the flask.
- Gently scrub the lower half of the flask (model half) with a mild detergent and rinse thoroughly with clean, hot

water. Post dam, if necessary; apply separator; allow the separator to dry.

- Prepare the denture base for the soft liner by relieving the acrylic tissue-bearing surface by 2mm or more. Liner can extend above the peripheral roll to any length.
- 5. Eliminate severe undercuts and roughen areas of denture base to be relined.
- Gently scrub the upper half of the flask (denture half) and rinse with hot water. Apply separator to stone or plaster; let dry.

Measuring & Mixing:

 To measure: use the graduated glass vials marked "Powder" and "Liquid." You can control the liner's softness by modifying the powder/liquid ratio as shown in the chart above.

Note: At a 2:1 ratio, liner is the softest. A light powdering of liner's surface will absorb any excess liquid.

 Pour powder (all at once) into the liquid in mixing cup; *Stir very slowly* (to avoid the introduction of bubbles) until all of the powder particles are totally moistened. The mixture consistency instantly turns "sticky" and "honey-like."

Application:

- 9. *Immediately,* spread the mixture onto the totally dry denture base surface.
- Close the flask or jig for curing. In jig, use fingertip coated with the mixing liquid to taper and smooth any excess material 3mm onto labial and buccal surfaces.

Curing:

 Place flask onto a press; slowly apply pressure until the flask is completely closed.

Note: Do not trial pack the soft liner.

12a. In a flask: Place flask in a curing unit filled with boiling

water (212°F/100°C) for 15 minutes.

12b. In a jig: Place jig in a curing unit or in a pressure pot at (20psi/1.4 bar) in steaming hot water (between 122°F/50°C to 165°F/74°C) for 10 minutes.

Finishing:

- Remove cured denture from flask or jig; chill it a few minutes in an ice water bath to temporarily harden the soft liner for easy trimming.
- Remove excess flash with sharp scissors, scalpel or suitable rotary instrument (i.e. acrylic bur, rubber point or finishing stone). Feather taper liner 3mm onto labial and buccal surfaces.
- 15. If desired, finish with a wet rag wheel and pumice to further smooth the surface. Do not high-shine the liner using a buff wheel as PermaSoft Sealer provides a high-gloss finish.

Sealing:

 Dry the liner surface using air or warm air blower to remove all surface moisture. Apply a generous coat of PermaSoft Sealer over the <u>totally dry</u> soft liner and air dry for 2+ minutes. Repeat procedure adding a second coating. A third coat of PermaSoft Sealer can be applied on non-retentive fitting surfaces.

Additional Information:

Note: Provide Patient Care Card to instruct care & cleaning of the soft liner.

Note: To adjust, refit or repair: roughen the surface, apply a fresh mix of soft liner, follow directions above for Application, Curing, Finishing and Sealing.

Note: The Powder is available in a "clear" shade which can be used to retain transparent acrylic mouth guards, bite plates and splints, to protect veneers, and as a gasket connector around teeth.

Lining a New Denture:

Preparation:

- Invest denture, wax-up and boil-out in the usual manner. Apply separator to denture half of mould. Allow the separator to dry.
- Form a spacer on the model from 1mm to 2+mm in thickness. Allow spacer to overlap the peripheral roll 3mm onto the labial and buccal surfaces. Soft liner can extend above the peripheral roll to any length.
- With spacer in place, trial pack the acrylic with dry sheets. After final packing of acrylic, allow 20 minutes to "snap set" the acrylic while flask is in the press.
- Open flask, remove spacer and clean model. Apply separator onto the model-side stone surfaces. Allow the separator to dry.

Measuring & Mixing Application:

(Follow instructions on page 2.)

Curing:

Cure per manufacturer's instruction for the "new" acrylic resin being used.

Finishing and Sealing:

(Follow instructions on page 3.)

CHAIRSIDE TECHNIQUE

Density	Ratio (P:L)	Powder	Liquid	Applications
Softest	2:1	8cc	4cc	Post-surgical prostheticsCushion for sensitive tissue
Standard Lining	2.5:1	10cc	4cc	•Complete denture relines •Partial denture stabilization •Overdenture retained on healing caps
Firm	3:1	12cc	4cc	•Overdenture retained by ball abutments, bar connectors or teeth.

5.

Preparation:

- Relieve all undercuts and remove 2mm or more of acrylic on the tissue side of the denture to make room for the soft liner.
- 2. Roughen the peripheral roll plus 3mm of the buccal and labial surfaces.
- Clean and dry the areas where the soft liner is to be applied. Use petroleum jelly or a water soluble substitute to coat the interproximal surfaces that are not meant to be lined. This will ease finishing.

Measuring & Mixing:

 To measure: Use the graduated glass vials marked "Powder" and "Liquid." You can control liner's softness by modifying the powder/liquid ratio as shown in the chart above.

> Note: At a 2:1 ratio, liner is the softest. A light powdering of liner's surface will absorb any excess liquid.

Pour powder (all at once) into the liquid in mixing cup; *Stir very slowly* (to avoid the introduction of bubbles) until all of the powder particles are totally moistened. The mixture consistency instantly turns "sticky" and "honey-like."

Application:

- 6. *Immediately*, spatulate and spread the mixture onto the totally dry denture.
- Apply lubricant to patient's lips or ask patient to moisten lips as the soft liner does not adhere to wet areas.

Note: For patients with sore spots or tissue/taste sensitivity, rinse the mouth for 20 seconds with an anesthetic mouth rinse.

 Place denture in the mouth and instruct the patient to close gently into occlusion for one minute while performing muscle moulding at the same time, if desired.

- Remove denture from the mouth. The soft liner should completely overlap the peripheral roll.
- Use a fingertip coated with the mixing liquid to taper and smooth the excess material 3mm onto the labial and buccal surfaces; then cure immediately.

Curing:

- Place the denture, reline side up, into a cup filled with steaming Hot Water (between 122°F/50°C to 165°F/74°C) and cure for 10 min. If available, place in a pressure pot; cure in Hot Water (between 122°F/50°C to 165°F/74°C) at (20 psi/1.4 bar) for 10 min.
- 12. After curing, chill the denture in Cold Water or Ice Water or spray the liner's surface with a skin refrigerant to temporarily harden the soft liner for easy trimming.

Finishing & Sealing:

- Remove excess flash with sharp scissors or scalpel. Feather taper the material onto the labial and buccal surfaces with an acrylic bur and smooth with a large rubber point or finishing stone.
- 14. If desired, finish with a wet rag wheel and pumice to further smooth the liner surface. Do not high-shine the soft liner.

15. Dry the liner surface using air or warm air blower to remove all surface moisture. Apply a generous coat of PermaSoft Sealer over the <u>totally dry</u> soft liner and air dry for 2+ min. Repeat procedure adding a second coating. A third coat of PermaSoft Sealer can be applied on non-retentive fitting surfaces.

> DO NOT place denture in patient's mouth until PermaSoft Sealer is completely dry and rinsed.

Patient Delivery:

Give patient a Patient Care Card to instruct him/her on care and cleaning of the soft liner.

- 1) Soak <u>only 10 min.</u> in denture cleaner.
- 2) Warn patient not to scrub the soft liner with a hard-bristle brush; and
- Request annual re-sealing of soft liner and dental examination to assure proper fit.

Note: To adjust, refit or repair; roughen the surface, apply a fresh mix of soft liner, insert, cure, finish and re-seal.

Note: Liner will cure in 5 minutes in-the-mouth for thin, small area relines.

Note: The Powder is available in a "Clear" shade which can be used to retain transparent acrylic mouth guards, bite plates and splints, as a gasket connector around teeth, and to fill voids to eliminate food traps.

Implant Overdenture Technique:

This patented implant overdenture technique was developed to aid in the progressive healing process following the surgical placement of implants. It is well suited for this chairside application due to one's ability to vary the liner's degree of softness, (see mixing ratios and applications in chart on page 4.)

Post-Surgical Placement:

After a one to two week interval following the implant placement, line the tissue side of the overdenture for a soft, light load.

Note: Initially, use softest liner mix ratio of 2 parts powder to 1 part liquid.

After suture removal, block out suture line (indentation) with dry foil or suitable material and reline following the Chairside Technique. Make sure soft material does not interfere with healing site or tissue flap. This soft liner cushions tender areas and its sealer provides a nonabsorbent, hygienic surface.

Healing Cap Exposure:

After an appropriate implant integration phase, perform the "second stage" reline. This requires a new application of soft liner to the relieved tissue side to anchor over healing caps.

Note: Use the standard liner mix ratio of $2\frac{1}{2}$ parts powder to 1 part liquid.

This Healing Cap overdenture enables a "gradual healing load" with light functional stimulus to the implant. This thin area reline will cure in-the-mouth in 5+ minutes.

Long Term Retention:

After attachment of ball abutments or bar connectors, reline overdenture to form gasket over balls or bars "without" O-rings or clips.

Note: Use the firmest liner mix ratio of 3 parts powder to 1 part liquid.

The liner absorbs torque pressure and provides retention for long term service with easy chairside adjustment.

TECHNIQUE FOR CLEAR POWDER

Density	Ratio (P:L)	Powder	Liquid	Applications
Standard Lining	2.5:1	10cc	4cc	Retain and cushion of clear acrylic appliances, such as night guards, bite plates, splints, TMJ & sleep apnea devices
Firm	3:1	12cc	4cc	 Gasket in a removable denture for retention on existing teeth Fills voids beneath clasps and under retainers to eliminate food traps on acrylic prosthesis

Introduction

Long-lasting and easy to use, PermaSoft Clear Powder possesses the same working characteristics as PermaSoft Pink Powder. Once cured, the transparency of PermaSoft Clear Powder makes it ideal for use with any clear acrylic resin appliance (e.g. night guards, bite plates) or as a gasket connector around teeth in a removable denture.

Soft Lining of Clear Acrylic Appliance

- 1. Process acrylic appliance in usual manner.
- Relieve 2mm of acrylic from the occlusal surface of the appliance to make room for the soft lining.

Note: Maintain an acrylic border no thinner than 1mm to support soft lining.

- Clean and thoroughly dry areas where soft liner is to be applied.
- 4. To place soft lining, refer to directions for "Laboratory

Technique" or "Chairside Technique".

Creating a Gasket in Removable Denture

- Create a hole in denture with 2mm to 3mm of space around existing tooth or teeth to allow room for PermaSoft gasket.
- Roughen 3mm area surrounding the newly-created hole(s) on all surfaces where the soft liner will adhere.
- To measure: Use the graduated glass vials marked "Powder" and "Liquid". For this application we recommend a 3:1 Powder-to-Liquid ratio.
- Apply lubricant to all areas where you do not want the soft liner to adhere.
- 5. Follow Mixing & Measuring instructions in Directions for Use.
- Spatulate mixture onto the tissue side of the totally dry denture beneath created hole(s).

- Seat the denture over the existing tooth or teeth. The soft liner will flow out through the hole.
- Use a fingertip coated with the mixing liquid to taper and smooth excess soft liner 3mm onto the labial and buccal surfaces.
- 9. Follow Curing, Finishing & Sealing instructions in Directions for Use.

Soft Lining of New Appliance

Follow Directions for Use, "Laboratory Technique," Lining New Denture, in order to place PermaSoft Clear inside transparent acrylic appliances such as a night guard or bite plate. Make sure to leave 1+mm of acrylic border to support the soft material inside the arch.