

Revised: November 2020 37391/3920

Your permanent denture soft liner solution!

If your goal is to have an excellent result when placing a soft liner each and EVERY time, then...

PLEASE take the time to read the instructions thoroughly and follow them exactly.

www.easysoftliner.com

WARNINGS

Please note: Easysoftliner[™] requires a denture base material that contains PMMA (Poly Methyl Methacrylate) to ensure optimal bonding, in use with Easysoftliner Adhesive/ Bonding Agent. If you are unsure if the denture base contains PMMA, it is highly recommended to check bonding prior to use. In some cases where the PMMA content in the denture base material is low, it is recommended to increase the length of bonding time to 2 hours at 50°C/120°F water temperature.

- Do not use EasySoft liner™ relining material as an impression material
- Do not use EasySoft liner™ products with other reliners, sealants or adhesives
- Close the bottle of EasySoft liner[™] adhesive immediately after use.

PRECAUTIONS

- The possibility of allergic reactions to the product in sensitive persons cannot be fully excluded.
- Do not leave any soft liner in the mouth that has not attached to the denture
- Avoid splattering this material onto clothing as it cannot be removed by dry cleaning.
- Certain local anesthetics, retraction solutions, mouth washes or H₂O₂ may impede the setting reaction.

COMPATIBILITY WITH OTHER MATERIALS

- Do not contaminate EasySoft liner™ (type "A" silicone) with polyether materials.
- As with all type A silicones, certain examination gloves may damage the platinum
- catalyst regardless of whether there is direct or indirect contact with the silicone material. This may result in EasySoft liner™ not achieving complete setting and final hardness.

TECHNICAL DATA

Total working time:	2 minutes 15 seconds
Intra-oral setting time:	3 minutes 15 seconds
Setting completed:	5 minutes 30 seconds
Linear dimensional change:	- 0.20 %
Elastic deformation:	99.5 %
Shore-A hardness (24hours):	28
Shelf life:	36 months
Storage temperature:	10-25 °C / 50-77 °F (Do not refrigerate)

INDICATIONS FOR USE

EasySoft liner™ can be used indirectly (laboratory processing) or directly (chairside) for fabricating a permanent soft lining material on the tissue bearing surface of a denture. EasySoft liner™ is recommended for:

IMPROVED PATIENT COMFORT!

- · for permanently soft linings
- for compensating for areas of mucous membrane with varying degrees of resiliency
- for relieving sharp bony ridges
- for relieving the operation site after placing implants
- for relining temporary restorations
- for conditioning the mucous membranes in cases with denture sores
- for fabricating and relining obturators

CAUTIONS:

Do not use after the expiration date.

HANDLING INSTRUCTIONS FOR RELINING DENTURES ARE IN THIS SHEET

- · Do not leave remains of soft liner in the mouth.
- Do not swallow the material! If swallowed: consult a doctor if problems arise or persist.
- Avoid contact with eyes. If accidental contact with eyes occurs, rinse immediately & thoroughly with an eyewash or water. Consult a doctor if problems arise or persist.
- The product does not usually cause allergic reactions. However, for sensitive persons, an allergic reaction to the product cannot be ruled out.

- Also, if used on patients whose immune system is impaired, or on those who are suffering from a variety of other diseases (such as diabetes mellitus) or those who are taking medications including antibiotics or cortisone, it has been observed in rare cases that microorganisms (e.g. Candida Albicans) may colonize the soft lining. In such cases, whenever the lining of the dentures is replaced, the soft lining should not be used since the recolonization by microorganisms is likely if the patient status remains unchanged.
- Increased colonization by microorganisms and the development of denture stomatitis have been observed in patients due to inadequate oral hygiene and improper cleaning of soft-lined dentures.
- Please instruct the patient about adequate oral hygiene and provide him with the care
 instructions from the base set.
- Solutions used before the application of EasySoft liner™ (e.g., retraction solutions, mouth rinsing solutions) may interfere with the setting reaction of the relining material and must be removed by thorough spraying and drying.
- If gloves are worn when processing the material, they should first be tested for compatibility using a sample. Some types of gloves can disturb the activity of the catalyst.
- Should the silicone soft liner require adjustment, relieve the ar-ea liberally, and apply another coat of EasySoft liner[™]. Brush two coats of adhesive onto the exposed areas of acrylic only.
- When handling chemicals the usual precautions must be taken.
- Do not allow the material to enter the sewer or water system to avoid environ mental contamination.
- · Avoid contact with clothing, since the material cannot be removed by dry cleaning.

INSTRUCTIONS FOR USE

USING A RELINE JIG - EXISTING DENTURE

STEP 1

- Disinfect the reline impression using manufacturers instructions.
- Pour the impression using a high quality dental stone. Type IV stone and vacuum mixed is ideal.
- Mount the reline model onto the reline jig as usual.

STEP 2

• Once stone has set, remove denture from reline jig and trim denture for desired thickness of EasySoft liner™.

EasySoft liner™ requires a <u>minimum thickness of 1mm in order to achieve a proper</u> bonding and curing. Ideal thickness for patient comfort is 2 to 3 mm.

STEP 3

- ${\boldsymbol \cdot}$ Once the tissue bearing side and periphery of the denture has been reduced &
- roughened for adequate EasySoft liner™ thickness, clean the denture with monomer and place it back onto reline iig.
- Separate stone model with a stone to acrylic separator. Allow separator to dry completely.
- PLEASE NOTE: cleaning the denture with monomer at this stage is recommended to remove hand oils and debris. However, allow monomer to <u>completely</u> dry for several minutes before the EasySoft liner[™] adhesive is applied!
- Brush on EasySoft liner[™] adhesive where EasySoft liner[™] material is desired, wait 30 seconds. **DO NOT BLOW DRY.**
- Apply a second coat of adhesive to the areas where EasySoft liner™ material is desired. Allow adhesive to dry for the **full 2 minutes**.

DO NOT BLOW DRY.

- Ensure that the adhesive is applied beyond the prepared periphery. If there is no adhesive there will be no bonding of EasySoft liner™.
- Adhesive must be completely dried prior to applying EasySoft liner™ material.

STEP 4

- Apply EasySoft liner™ material uniformly with a dispensing gun and tip onto the model and the denture base.
- **TIP:** to prevent air voids being trapped in the EasySoft liner[™] material, keep the end of the tip in the material while dispensing it onto model and denture.

STEP 5

- Close the reline jig halves and tighten screws to apply pressure as usual.
- \bullet Place reline jig immediately into pressure pot immerse in water at 50°C / 120°F for a minimum of 35 minutes. No pressure required.

STEP 6

- TRIMMING OF EASYSOFT LINER™ AND USE OF SEALANT
- Once the EasySoft liner™ material has cured, remove the denture from reline jig, as usual.

• Use sharp scissors to cut excess EasySoft liner™ material at the periphery.

Use a rotary instrument (EasySoft liner[™] bur) to create a neat junction between the denture acrylic and the softliner.

- Final finishing shouldshould be carried out with the EasySoft liner™ polishing discs.
- Trimmed areas of acrylic can be polished with pumice, as usual.
- Clean EasySoft liner™ thoroughly with soap and water, then dry.

Remove any residual acrylic polishing paste prior to using the sealant.

If the paste cannot be removed entirely, use the EasySoft liner™ polishing disc to remove residual paste.

- Apply a thin layer of EasySoft sealant to trimmed areas of EasySoft liner™ only.
- It is advisable to place a small amount of EasySoft sealant into a small dappen dish and apply it with a clean brush.
- Once EasySoft sealant has been dispensed it must be used within 90 seconds.
- The sealant loses its adhesive properties after 7 minutes.

Immerse the denture for 30 minutes in 50°C/120°F warm water. It is not important to have denture under pressure during this step.

PLEASE NOTE: The silicone sealant does not attain its final mechanical properties until it has been at mouth temperature for 24 hours.

NEW DENTURE WITH SOFT LINER ONE INVESTMENT PROCEDURE

STEP 1

- Be sure when waxing up the new denture for investing, that the required thickness for both the acrylic base and EasySoft liner[™] is adequate.
- · Invest the wax denture in the flask
- When the investment stone is set, boil out and clean the model and investment stone in flask.
- Apply separating fluid to the stone and model (use a separator which forms a microfilm).
- Wait until the stone has completely cooled and separator is dry.

STEP 2

- In order not to damage the stone model from being damaged during
- processing of denture base material, apply a thin layer of a flexible silicone material to protect the entire surface of the model.

Placing the thin flexible silicone material is a very important step. The silicone ensures that the stone model is preserved during the processing of the acrylic base material. It allows for a second processing technique - EasySoft LinerTM using the same investment of flask.

- Once the flexible silicone material is set, close upper and lower flask together to ensure there is no interfence.
- · Trial pack or inject the acrylic into flask as usual.
- · Process acrylic base material according to manufacturer's instructions.
- · Cool acrylic and flask, as usual.
- Open the flask carefully without deflasking.

STEP 3

• It will not be possible to remove the denture from the flask at this stage.

- Drill even depth holes using a 2 or 3 mm round bur through the spacer into the entire tissue bearing surface of the denture.
- Discard the silicone spacer.
- The holes should be the depth of your desired EasySoft liner™ thickness.
- The multiple holes will guide you like a 'dot to dot' in your trimming of the base material.
- · Clean denture after trimming from all debris and hand oils.

recommended to remove hand oils and debris. However, allow monomer to **<u>completely</u>** dry for several minutes before the EasySoft liner[™] adhesive is applied!

- Brush on EasySoft liner[™] adhesive where EasySoft liner[™] material is desired, wait 30 seconds. **DO NOT BLOW DRY.**
- Apply a second coat of adhesive to the areas where EasySoft liner™ material is desired. Allow adhesive to dry for the **full 2 minutes.**

DO NOT BLOW DRY.

Ensure that the adhesive is applied beyond the prepared periphery. If there
is no adhesive there will be no bonding of EasySoft liner™.

Adhesive must be completely dried prior to applying EasySoft liner™ material.

STEP 4

• Apply enough EasySoft liner™ uniformly with a dispensing gun onto the model and the denture base.

DO NOT TRIAL PACK EasySoft liner™ material

- Close the flask and place back into the clamping press as used during base material processing. Apply enough pressure just to keep the 2 flask halves together tightly during EasySoft liner™ curing.
- Immerse the flask and clamp into water bath at 50°C / 120°F for a minimum of 35 minutes.

CHAIRSIDE - INITIAL PLACEMENT

- · Clean the denture base thoroughly with water and dry.
- Reduce the tissue bearing surface enough to allow for the desired thickness of EasySoft liner™.

EasySoft liner™ needs a minimum thickness of 1mm in order to achieve a proper bonding and curing.

- Apply a coat of EasySoft liner[™] adhesive and wait 30 seconds.
 DO NOT BLOW DRY.
- Apply a second coat of adhesive and allow it to dry for 2 minutes. DO NOT BLOW DRY.
- · Ensure that the adhesive is applied beyond the prepared periphery.
- Adhesive must be completely dried before applying EasySoft liner™ to the tissue bearing surface.
- Apply the EasySoft liner[™] on to the denture uniformly with a dispensing gun (to prevent air bubbles from being trapped, keep the end of the tip in the material as you dispense the material).
- · Insert the denture into the patient's mouth immediately.
- The functional excursions (border moulding) should be done.
- Intraoral setting time 5 minutes.
- Once the denture has been removed from the patient's mouth, immerse the denture with the soft lining into water at 50°C / 122°F for at least 15 minutes (no pressure pot is required) or allow 30 minutes for it to cure at room temperature.

PLEASE NOTE: The silicone sealant does not attain its final mechanical properties until it has been at mouth temperature for 24 hours. Please advice patient to use a super soft toothbrush in order to clean the soft lined denture.

To ensure excellent soft linings, the total working time and intraoral setting time must be adhered to exactly. Should the temperature of the material in storage deviate noticeably from 23°C / 74°F, the total working and setting times will be affected.

REPAIRING EASYSOFT LINER™

EasySoft liner[™] will adhere to itself without adhesive, providing the existing EasySoft liner[™] material is free of debris and hand oils and other contaminants. DO NOT use adhesive to add EasySoft liner[™] to EasySoft liner[™]!

New EasySoft liner[™] applied to repair the area, requires the same time and adhesive application instructions as required for all EasySoft liner[™] applications.

Safety Data Sheet EasySoft Liner™

1. Identification of the substance/preparation and company	9. Physical and c
 1.1 Product details Trade name: EasySoft liner catalyst paste + Base paste EasySoft liner silicone sealant catalyst paste + Base paste 1.2 Distributor details: Karlin Dental Distributors Inc. Tel:1-800-661-7429 211 Bowes Rd., Vaughan, Ontario Fax:(905)532-0704 ON L4K 1H8, Canada https://www.easysoftliner.com	 9.1 Appearance: Form: Colour: Catalyst paste Base paste: Odour: 9.2 Density: 1.1 – 9.3 Solubility in v
2. Hazards identification	9.4 pH-value: Neu 10. Stability and r
No special hazards have to be mentioned.	-
3. Composition/information on ingredients	10.1 Hazardous re
3.1 Chemical characterization:	11. Toxicological
Hardener paste: vinylpolysiloxane – filling material – polymethylhydrogensiloxane Base paste: vinylpolysiloxane – filling material – ppm platinum siloxane complex	11.1 Acute oral tox 11.2 Irritant effect 11.3 Irritant effect 11.4 Sensitization:
3.2 Additional information: No further information since neither hazardous substance nor hazardous compound.	12. Ecological inf
4. First aid measures	12.1 Environmenta into the environmenta
4.1 After contact with skin: No special measures necessary.4.2 After contact with eyes: Eye treatment by an physician.	13. Disposal cons
4.3 After ingestion: No special measures necessary.	13.1 Product: Dis
5. Fire-fighting measures	Dis
5.1 Suitable extinguishing media:	14. Transport info

9. Physical and chemical properties

9.1	Appearance:
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	Form:	paste	
	Colour:	, pink	
	Catalyst paste:	, pink transparent	
	Base paste:	colourless transparent	
	Odour:	odourless .	
.2	2 Density: 1.1 – 1.2 g/cm ³ at 20°C / 68°F		
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- 9.3 Solubility in water: Insoluble
- 9.4 pH-value: Neutral
- 10. Stability and reactivity

10.1 Hazardous reactions: No hazardous reactions known.

11. Toxicological information

- 11.1 Acute oral toxicity: 11.2 Irritant effect on skin:
- 11.3 Irritant effect on eyes:
- Non-irritant. Non-irritant. Non-sensitizing.

LD50: > 2000 mg/kg rat.

12. Ecological information

12.1 Environmental precautions: Do not discharge product unmonitored into the environment.

13. Disposal considerations

13.1 Product: Disposal in agreement with the Local Waste Disposal Authority.

14. Transport information

14.1 Road transport:

- GGVS/ADR: No hazardous goods.
 - Train GGVE/RID: No hazardous goods.
- 14.2 Marine transport:
 - IMDG/GGVSee-Code: No hazardous goods.
- 14.3 Air transport:

ICAO/IATA-DGR: No hazardous goods.

15. Regulatory information

15.1 Labelling: The product does not require a hazardous warning label.

16. Other information

This information is based on our present state of knowledge. It should not therefore be construed as guaranteeing specific properties of the products described or their suitability for a particular application.

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Water, foam, CO2, dry chemical extinguisher.

6. Accidental release measures

6.1 Methods for cleaning up/taking up: Pick up mechanically.

7. Handling and storage

- 7.1 Handling: No special measures necessary.
- 7.2 Storage: No special measures necessary. 18-23°C / 64-74°F Do not refrigerate.

8. Exposure controls/personal protection

8.1 General protective measures: No special measures necessary.

1. Identification of the substance/preparation and company

1.1 Product details Trade name:

EasySoft liner Adhesive

1.2 Distributor details: Karlin Dental Distributors Inc. Tel:1-800-661-7429 211 Bowes Rd., Vaughan, Ontario Fax:(905)532-0704 ON L4K 1H8, Canada https://www.easysoftliner.com

2. Hazards identification

When used as directed: None Highly flammable. Irritating to eyes and skin.

3. Composition/information on ingredients

Chemical characterization:

polymethyl methacrylate - copolymer - ethyl acetate

4. First aid measures

- 4.1 After inhalation: Remove the casualty into fresh air and keep calm.
- 4.2 After contact with skin: Wash off with soap and water. Remove contaminated clothing.
- 4.3 After contact with eyes: Rinse thoroughly with water and contact physician.
- 4.4 After ingestion: Contact physician immediately. Drink plenty of water.

5. Fire-fighting measures

5.1 **Suitable extinguishing media:** Extinguishing powder, foam.

6. Accidental release measures

- 6.1 Personal precautions: Ensure adequate ventilation. Keep away from sources of ignition, refrain from smoking. Do not inhale vapours/aerosols.
- 6.2 Environmental precautions: Do not discharge product unmonitored into the environment.
- 6.3 Methods for cleaning up/taking up: Pick up mechanically.

7. Handling and storage

- 7.1 **Handling**: Ensure adequate ventilation. Keep away from sources of ignition, refrain from smoking.
- 7.2 **Storage**: Keep container tightly closed and store in a dark well-ventilated place. Do not refrigerate.

8. Exposure controls/personal protection

8.1 General protective measures: Do not inhale vapours. Avoid contact with skin and mucous membranes.

9. Physical and chemical properties

9.1 Appearance:

Form: liquid Colour: colourless Odour: fruit-like

9.2 Changes in physical state: Boiling point: < 77°C / 171°F Flash point: - 4°C / 25°F Ignition temperature: 460°C / 860°F Explosion limit: 2.1 – 11.5 vol. % Vapour pressure: 97 hPa Density: 0.9 g/cm³ Solubility in water: insoluble (20°C / 68°F)

10. Stability and reactivity

10.1 Hazardous reactions: Vapours can form an explosive mixture with air.

11. Toxicological information

- 11.1 Acute oral toxicity: LD50: > 5000 mg/kg rat.
- 11.2 Irritant effect on skin: Has a degreasing effect on the skin.
- 11.3 Irritant effect on eyes: Irritations possible.

12. Ecological information

12.1 Environmental precautions: Do not discharge product unmonitored into the environment.

13. Disposal considerations

- 13.1 Product: Dispose remaining material at hazardous or special waste collection centres.
- 13.2 Packaging: Completely emptied packaging can be recycled.

14. Transport information

- 14.1 Road transport: GGVS/ADR: class 3 packing group II GGVE/RID: class 3 packing group II
- 14.2 Marine transport: IMDG/GGV Code: 3 EmS: 3-07 packing group II
- 14.3 Air transport: ICAO/IATA-DGR: class 3 packing group II
 14.4 Further information:
- UN-number: 1173 Correct technical name: ethyl acetate

15. Regulatory information

15.1 Hazard symbols:

Hazard statements: H225 Highly flammable liquid and vapour. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H336 May cause drowsiness or dizziness. 0624 Keep away from sunlight 0533 Store at indicated temperature 0626 Keep away from rain



16. Other information

This information is based on our present state of knowledge. It should not therefore be construed as guaranteeing specific properties of the products described or their suitability for a particular application. Results are furnished to the best of our knowledge, subject to technical changes within the framework of product development. However, users must comply with and consider all recommendations and information in connection with any use.

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