

## Silicone-based soft denture liner

**SOFRELINER TOUGH S Soft****ENGLISH**

Carefully read all of these instructions before using SOFRELINER TOUGH S.

**■ PRODUCT DESCRIPTION AND GENERAL INFORMATION**

1. SOFRELINER TOUGH S is an addition-cured silicone chairside soft lining material for non-volatile denture.
2. SOFRELINER TOUGH S Kit contains PASTE, PRIMER and other accessories such as mixing tips, drip nozzle, cup brush, COARSE POINT (Black), FINISHING WHEEL (Brown).
3. PRIMER is used solely for bonding to the acrylic surfaces. It cannot be used to bond nylon, metal and silicon surfaces. PASTE is dispensed in an autmix cartridge delivery system. The material sets in 5 minute introradically or 20 minutes at room temperature (23°C / 73.4°F) and has no odor or taste.

**■ INDICATIONS**

1. For pain caused by sharp ridges of alveolar bone and mucous atrophy.
2. Poor retention caused by extreme dryness.
3. Major undercuts or maxillary mandibular tori.
4. Removal of denture base before the final attachment is placed.
5. Temporary lingual or tissue conditioning.

**■ CONTRAINDICATIONS**

SOFRELINER TOUGH S is contraindicated in patients allergic to or hypersensitive to silicone and platinum compounds and should NOT be used on such patients.

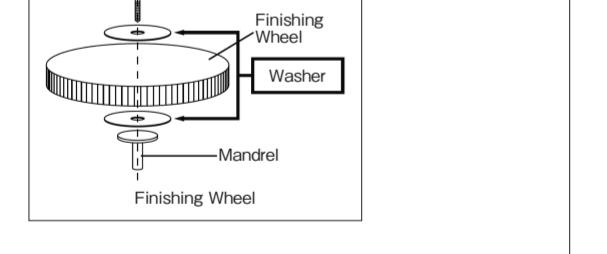
**■ PRECAUTIONS**

1. SOFRELINER TOUGH S is designed for sale and use by licensed dental care professionals only. It is not designed for sale nor is it suitable for use by non-licensed dental professionals.
2. Use SOFRELINER TOUGH S only as instructed herein. DO NOT use SOFRELINER TOUGH S for any application other than those noted in these instructions.
3. Do NOT use SOFRELINER TOUGH S if the safety seal is broken or if it appears the contents have tampered with.
4. PRIMER contains ethylacetate, which is a highly flammable and volatile solvent. Do not expose the PRIMER to open flame. Use in a ventilated room during use and close the cap tightly after use.
5. If patient experiences an allergic reaction or sensitivity to SOFRELINER TOUGH S, such as a dermatitis break, remove the prosthesis and discontinue its use immediately.
6. Wear non-latex examination gloves at all times while using SOFRELINER TOUGH S to avoid the possibility of allergic reactions. Latex gloves may also inhibit the setting of SOFRELINER TOUGH S. If SOFRELINER TOUGH S PRIMER comes in contact with the examination gloves, immediately dispose of the examination gloves and wash hands thoroughly with water.
7. Avoid contact with eyes. In case of contact with eyes, thoroughly flush eyes with water, and immediately contact a physician.
8. Avoid contact of unset chemical with skin. In case of contact with skin, clean affected area with rubbing alcohol, then thoroughly flush with water.
9. Avoid contact of unset chemical with clothing. In case of contact with clothing, do not wipe the material. Allow it to set and then peel it off.
10. DO NOT allow excess materials to flow down the patient's trachea or esophagus. Aspirated or ingested SOFRELINER TOUGH S PASTE can cause asphyxiation or other injury. Immediately remove the material from the mouth or nose by rinsing with copious amounts of water down the patient's throat. SOFRELINER TOUGH S is not radioactive, and radiosensitivity will not detect aspirated or ingested material. In case of an elderly patient whose reflex ability is compromised, set the chair in an upright position and instruct the patient to breathe through the nose in order to prevent the material from entering the airway.
11. DO NOT mix SOFRELINER TOUGH S with any materials not noted in these instructions.
12. After the use of SOFRELINER TOUGH S, clean the materials from the cartridge at the time of purchase. Wipe off the excess paste on the tip of the cartridge with a clean cloth or tissue each time before using a new mixing tip or replacing the cartridge cap.
13. Always clean the spatulas, brushes and cups with alcohol after each use to avoid cross contamination of the materials.
14. Instruct patients in accordance with the PATIENT PRECAUTIONS contained in the last section of these instructions.
15. To avoid inhaling dust while finishing, always wear a mask recommended by federal and/or local regulations.
16. Refer to the manufacturer's instructions for all products mentioned in this instruction manual that are not included in this kit.
17. As much as possible, avoid contact SOFRELINER TOUGH S with oral mucous membrane other than the region to be lined. Instruct patients to rinse their mouth with adequate amount of water after the treatment.
18. Do NOT use the PRIMER in direct contact with plastic materials, contact may dissolve some types of plastic.

**■ NOTES FOR USE**

1. In the case of a poor fitting denture, first line the denture with an acrylic material, such as TOKUYAMA REBASE II, chairside hard denture lining material, or any other laboratory/inject procedures to improve the fit.
2. In the case of an old worn denture, the surface to be lined should be first lined with new self-curing resin in the old worn resin such as oil or water lowers the adhesion of SOFRELINER TOUGH S.
3. If the SOFRELINER TOUGH S PRIMER becomes thick due to volatilization, do not use it as the adhesive strength may be reduced.
4. Regarding the brush for the PRIMER, wipe off the tip with a moist-soaked cotton swab or gauze after each use.
5. Do not use pastes by hand, doing so may cause air bubbles to be incorporated into the paste, which could result in deterioration, staining and unpleasant odors.
6. Avoid contact SOFRELINER TOUGH S with the materials below, as they may inhibit the setting of SOFRELINER TOUGH S.
7. Silicon-based impression materials, eugenol containing materials, polysulfide rubber impression materials, natural rubber glubes, other manufacturer's soft lining materials and uncured acrylic resin.
8. The material sets in 5 minutes introradically or 20 minutes at room temperature (23°C / 73.4°F). After 24 hours the liners turn slightly firmer. The finishing procedure can be performed immediately after the removal of the liner from the mouth or a gypsum model.
9. Soaking the denture in warm water before heavy bleach may alter the color of SOFRELINER TOUGH S; however, it will not affect its performance.
10. Instruct patient to clean the denture as described in PATIENT PRECAUTIONS.
11. Since silicone-based fit checking material sticks to SOFRELINER TOUGH S, apply Vaseline on the surface prior to use.
12. Refer to following tools for shape adjustment and finishing.

Stages	Tools	Shapes
Trimming	Sharp scalpel	Slightly rounded blade
Shape Adjustment	COARSE POINT (Black)	Round tapered end
Finishing	FINISHING WHEEL (Brown)	Wheel
Relief	DIAMOND ROUND BUR	Round

**■ STORAGE**

1. Store SOFRELINER TOUGH S at a temperature between 0 - 25°C (32 - 77°F).
2. Avoid direct exposure of SOFRELINER TOUGH S to heat, open flame, humidity and sun.
3. Do not use SOFRELINER TOUGH S after the indicated date of expiration.
4. DO NOT leave SOFRELINER TOUGH S unnecessarily within the reach of patients and children to avoid being swallowed by mistake.

**■ DISPOSAL**

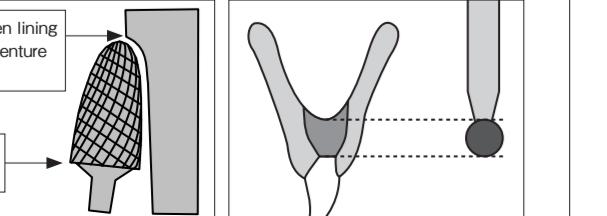
1. To dispose of the PASTE, dispense unused paste from the cartridge and allow it to set prior to disposal.
2. The remaining PRIMER liquid should be absorbed in an inert absorbent material such as glass cotton, and disposed of in accordance with local regulations.

**■ CLINICAL APPLICATION OF SOFRELINER TOUGH S INTRAORAL****LINING METHOD**

In most cases the optimum thickness of SOFRELINER TOUGH S should be 1-2 millimeter. If a thickness of over 2 millimeters is required, the area should first be lined with TOKUYAMA REBASE II, chairside hard denture liner, to obtain sufficient denture base. Excessive removal of denture resin could cause denture to fracture and weaken.

Check initial condition by inspection and palpation. Remove denture from patient's mouth and clean the area to be lined with soap and water. Rinse thoroughly and air-dry the denture surface completely. Grind the tissue side of the denture with a cross cut carbide bur to the proper depth. (See Figure 1). Remove the grinding dust with a dry brush or dry-fine-resin.

Note: When the border is placed within the flange of denture base, the grind the tissue side of the denture with round bur (for acrylic resin) to the proper depth (See Figure 2).

**■ Dispensing the PRIMER**

Open the bottle of PRIMER. Attach the drip nozzle to the bottle. Dispense an adequate amount of PRIMER into the dropper. Replace the cap, closing the bottle tightly immediately after dispensing.

**■ Applying the PRIMER**

Using the brush for the PRIMER, apply a thin, even coat of PRIMER on the denture surface where SOFRELINER TOUGH S is to be lined. Do not miss any areas where the PRIMER should be applied since this may cause poor adhesion. Then air-dry the surface thoroughly until no visible liquid remains.

**■ Dispensing the PASTE**

Load the SOFRELINER TOUGH S cartridge into a dispenser (sold separately). Open the cartridge cap of PASTE. Attach the mixing tip to the cartridge by aligning the notches, push it onto the cartridge, rotating the mixing tip clockwise 90 degrees.

**■ Applying the PASTE**

Extrude the mixed paste onto the tissue side of the denture. Using a spatula spread the paste evenly across all surfaces where the PRIMER was applied.

Note: If any part of the primed surface is not covered with paste in this stage, the area may be contaminated by saliva when it is inserted into the mouth, thus causing low adhesion.

**■ Internal inspection**

Since saliva excess saliva from patient's mouth. Within 1.5 - 2 minutes after mixing PASTE, PRIMER will turn to an adequate viscosity. Placing the denture in the patient's mouth, have the patient occlude very gently with centric occlusion with the proper vertical dimension. Check for any excess SOFRELINER TOUGH S in the patient's mouth, and remove immediately if present. Advise patient to exert denture pressure if he/she feels SOFRELINER TOUGH S is too stiff or causes discomfort.

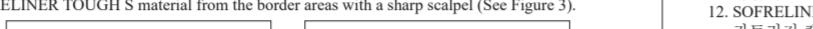
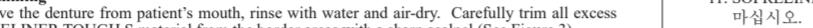
Note: If the patient feels uncomfortable, add a small amount of water to the denture.

**■ External inspection**

When the denture is inserted into the mouth, the patient should feel comfortable and pain-free.

**■ Trimming**

Remove the denture from patient's mouth, rinse with water and air-dry. Carefully trim all excess SOFRELINER TOUGH S material from the border areas with a sharp scalpel (See Figure 3).

**■ Coarse Pointing**

Shape the denture with COARSE POINT (Black) by applying light pressure not to exceed 15.000 rpm allowing the point to move in a small circle. For finishing, use the FINISHING WHEEL (Brown).

Note: Rotate the COARSE POINT and the FINISHING WHEEL from the lined area to the unlined area.

**■ Diamond Round Bur**

Remove the denture from patient's mouth, rinse with water and air-dry. Carefully trim all excess SOFRELINER TOUGH S material from the border areas with a sharp scalpel (See Figure 3).

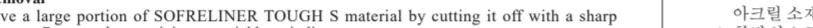
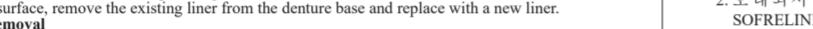
**■ Finishing**

For shaping, use the COARSE POINT (Black), by applying light pressure not to exceed 15.000 rpm allowing the point to move in a small circle. For finishing, use the FINISHING WHEEL (Brown), by applying light pressure not to exceed 8.000 rpm.

Note: Rotate the COARSE POINT and the FINISHING WHEEL from the lined area to the unlined area.

**■ Removal**

Remove the denture from patient's mouth, rinse with water and air-dry. Carefully trim all excess SOFRELINER TOUGH S material from the border areas with a sharp scalpel (See Figure 3).

**■ Clinical Application of SOFRELINER TOUGH S Laboratory Lining Method****1. Examine the denture**

Check initial condition by inspection and palpation. Examine the area where needs relief.

**2. Examination of the denture**

If the denture is worn or old, line the denture first using TOKUYAMA REBASE II, chairside hard denture lining material. The hard lining material should be applied in the appropriate thickness so that the new material is ground down according to the procedure in step 4, a newly lined layer of lining material is left on the denture bearing area, allowing SOFRELINER TOUGH S to adhere to it.

**3. Fabrication of a gypsum model**

Take an impression with the patient biting on the denture, then pour a stone slurry onto the impression. Make a stone index of the teeth and mount the denture on the index of a lining jig.

Relieve the stone model with wax in the region where may cause pain in the mouth. Apply a separating medium on the gingival area of the gypsum model so the lining material will not adhere to it.

**4. Preparation**

Grind the tissue side of the denture with a cross cut carbide bur to the proper depth.

Bevel the denture to allow 1 millimeter of material to roll over the borders (See Figure 1).

Remove the grinding dust with a dry brush or dry-fine-resin.

Note: Use of a round bur makes it easy to remove a uniform depth of resin. The diameter of

the bur will serve as a guide for depth.

**5. Dispensing the PRIMER**

Open the bottle of PRIMER. Attach the drip nozzle to the bottle. Dispense an adequate amount of PRIMER into the dropper, cap the bottle tightly immediately after dispensing.

**6. Applying the PRIMER**

Using the brush for the PRIMER, apply a thin, even coat of PRIMER on the denture surface where SOFRELINER TOUGH S is to be lined. Do not miss any areas where the PRIMER should be applied since this may cause poor adhesion. Then air-dry the surface thoroughly until no visible liquid remains.

**7. Dispensing the PASTE**

Load the SOFRELINER TOUGH S PASTE cartridge into a dispenser (sold separately). Open the cartridge cap of PASTE. Attach the mixing tip to the cartridge by aligning the notches, push it onto the cartridge, rotating the mixing tip clockwise 90 degrees.

**8. Applying the PASTE**

Extrude the mixed paste onto the surface where the PRIMER has been applied. Position the paste both on the mucosal side of denture and stone model.

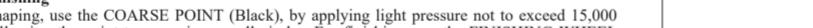
**9. Reattachment**

Reattach the denture onto its gypsum stone model and press it with the lining jig. Leave undressed for 20 minutes at room temperature (23°C / 73.4°F).

Note: If the material is sticky, soak the denture in warm water at 40°C to 50°C (104°F to 122°F) for 5 minutes with the lining jig.

**10. Trimming**

Remove the denture from the gypsum model. Carefully trim all excess SOFRELINER TOUGH S material from the border areas with a sharp scalpel (See Figure 3).

**11. Finishing**

For shaping, use the COARSE POINT (Black), by applying light pressure not to exceed 15.000 rpm allowing the point to move in a small circle. For finishing, use the FINISHING WHEEL (Brown).

Note: Rotate the COARSE POINT and the FINISHING WHEEL from the lined area to the unlined area.

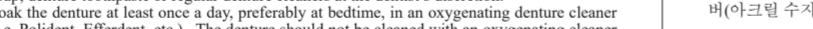
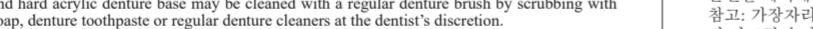
**12. Coarse Pointing**

Shape the denture with COARSE POINT (Black) by applying light pressure not to exceed 15.000 rpm allowing the point to move in a small circle. For finishing, use the FINISHING WHEEL (Brown).

Note: Rotate the COARSE POINT and the FINISHING WHEEL from the lined area to the unlined area.

**13. Diamond Round Bur**

Remove the denture from patient's mouth, rinse with water and air-dry. Carefully trim all excess SOFRELINER TOUGH S material from the border areas with a sharp scalpel (See Figure 3).

**14. Finishing**

For shaping, use the COARSE POINT (Black) by applying light pressure not to exceed 15.000 rpm allowing the point to move in a small circle. For finishing, use the FINISHING WHEEL (Brown).

Note: Rotate the COARSE POINT and the FINISHING WHEEL from the lined area to the unlined area.

**15. Removal**

Remove the denture from patient's mouth, rinse with water and air-dry. Carefully trim all excess SOFRELINER TOUGH S material from the border areas with a sharp scalpel (See Figure 3).

