

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

- SOFRELINER TOUGH S is an addition-cured silicone chairside soft lining material for removable dentures. SOFRELINER TOUGH S conforms to both ISO 10139-2 "Soft lining materials for removable dentures Part 2: Materials for long-term use" and ISO 10139-1 "Soft lining materials for removable dentures Part 1: Materials for short-term use".
- SOFRELINER TOUGH S Kit contains PASTE, PRIMER and other accessories such as mixing tips, drip nozzle, drip cup, brushes, COARSE POINT (Black), FINISHING WHEEL (Brown).
- PRIMER is used solely for bonding to the acrylic surfaces. It cannot be used to bond nylon, metal and silicone surfaces. PASTE is dispensed in automix cartridge delivery system. The material sets in 5 minute intraorally or 20 minutes at room temperature (23°C / 73.4°F) and has no odor or taste.

INDICATIONS

- For pain caused by sharp ridges of alveolar bone and mucous atrophy.
- Poor retention caused by extreme ridge atrophy.
- Major undercuts or maxillary / mandibular tori.
- Retention of overdentures before the final attachment is placed.
- Temporary lining 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.

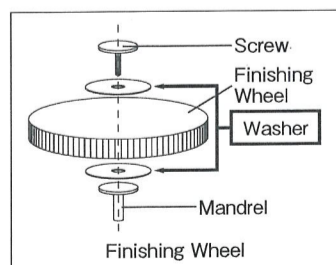
PRECAUTIONS

- 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-dental care professionals.
- Use SOFRELINER TOUGH S only as instructed herein. DO NOT use SOFRELINER TOUGH S for any application other than those noted in these instructions.
- DO NOT use SOFRELINER TOUGH S if the safety seal is broken or if it appears the contents have been tampered with.
- 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.
- If patient experiences an allergic reaction or sensitivity to SOFRELINER TOUGH S, such as a dermatitis outbreak, remove the prosthesis and discontinue its use immediately.
- 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.
- Avoid contact with eyes. In case of contact with eyes, thoroughly flush eyes with water, and immediately contact a physician.
- Avoid contact of unset chemical with skin. In case of contact with skin, clean affected area with rubbing alcohol, then thoroughly flush with water.
- Avoid contact of unset materials with clothing. In case of contact with clothing, do not wipe the material. Allow it to set and then peel it off.
- 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 any excess lining material from the palatal area to avoid material flowing down the patient's throat. SOFRELINER TOUGH S is not radiopaque, and radiographs 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.
- DO NOT mix SOFRELINER TOUGH S with any materials not noted in these instructions.
- After using SOFRELINER TOUGH S cartridge, the mixing tip must be replaced with the cartridge cap that comes with the cartridge at the time of purchase. Wipe off the excess paste on the tip of cartridge with a clean cloth or tissue each time before using a new mixing tip or replacing the cartridge cap.
- Always clean the spatula, brushes and cups with alcohol after each use to avoid cross contamination.
- Instruct patients in accordance with the PATIENT PRECAUTIONS contained in the last section of these instructions.
- To avoid inhaling dust while finishing, always wear a mask recommended by federal and/or local regulations.
- Read and follow the manufacturers' instructions for all products mentioned in this instruction manual that are not included in this kit.
- 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.
- Do not place the PRIMER in direct contact with plastic materials, contact may dissolve some types of plastic.

NOTES FOR USE

- 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/indirect procedures to improve the fit.
- In the case of an old worn denture, the surface to be lined should be first lined with new acrylic material since the materials absorbed in the old worn resin such as oil or water lowers the adhesion of SOFRELINER TOUGH S.
- If the SOFRELINER TOUGH S PRIMER becomes thick due to volatilization, do not use it as the adhesive strength may be reduced.
- Regarding the brush for the primer, wipe off the tip with alcohol-soaked cotton swab or gauze after each use. Contaminated brush can lower the adhesion of SOFRELINER TOUGH S.
- Do not mix pastes by hand, doing so may cause air bubbles to be incorporated into the paste, which could result in deterioration, staining and unpleasant odors.
- Avoid contact SOFRELINER TOUGH S with the materials below, as they may inhibit the setting of SOFRELINER TOUGH S:
Silicone-based impression materials, eugenol containing materials, polysulfide rubber impression materials, natural rubber gloves, other manufacturer's soft lining materials and uncured acrylic resins.
- The material sets in 5 minutes intraorally or 20 minutes at room temperature (23°C / 73.4°F). After 24 hours the liner turns slightly firmer. The finishing procedure can be performed immediately after the removal of the newly lined denture from the mouth or a gypsum model.
- Soaking the denture in solutions containing heavy bleach may alter the color of SOFRELINER TOUGH S; however, it will not affect its performance.
- Instruct patient to clean the denture as described in PATIENT PRECAUTIONS.
- Since silicone-based fit checking material sticks to SOFRELINER TOUGH S, apply Vaseline on the surface prior to use.
- If there is a fracture in the finished liner, completely remove the liner and repeat the procedure.
- 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 (sold separately) | Round |

**STORAGE**

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

DISPOSAL

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

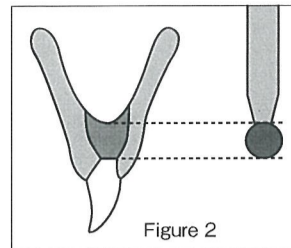
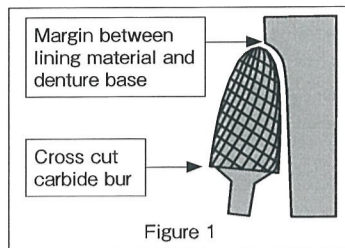
CLINICAL APPLICATION OF SOFRELINER TOUGH S INTRAORAL LINING METHOD

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.

1. Preparation

Check intraoral 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. Bevel the borders of 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 oil-free air.

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

**2. Dispensing the PRIMER**

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

3. 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.

4. 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.

5. Applying the PASTE

Extrude the mixed paste evenly on 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.

6. Intraoral insertion

Suction any excess saliva from patient's mouth. Within 1.5 - 2 minutes after mixing SOFRELINER TOUGH S the material will turn to an adequate viscosity. Placing the denture in the patient's mouth, have the patient occlude very gently into 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 patients to alert the dentist immediately if he/she feels SOFRELINER TOUGH S material or any substance flowing toward the throat.

Note: To line upper dentures with SOFRELINER TOUGH S, insert the denture from the posterior palatal region to avoid flow of SOFRELINER TOUGH S material down the patient's throat. When lining the palatal region, avoid applying too much Paste on the surface to be lined and insert the denture in the mouth as quickly as possible to avoid making the liner too thick.

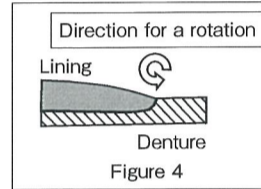
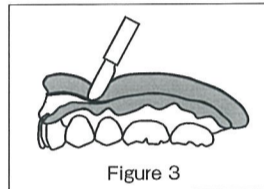
7. Border molding

Pull the cheeks very gently to mold the border of vestibule area while the patient is gently occluding. If patient salivates, suction the saliva and instruct the patient to resume occluding gently. SOFRELINER TOUGH S should be allowed to set intraorally for at least 5 minutes.

Note: Removal prior to 5 minutes may distort the liner.

8. 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).

**9. 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 denture area so as not to break the margin region (See Figure 4).

Use DIAMOND ROUND BUR (sold separately) or any suitable bur for relief.

10. Readjustment

In case of tissue conditioning, revisits should be made a few days after the initial treatment. Readjust the denture according to the procedure of section 9. If new material is to be added to the lined surface, remove the existing liner from the denture base and replace with a new liner.

11. Removal

Remove a large portion of SOFRELINER TOUGH S material by cutting it off with a sharp instrument. Remove the remaining material by grinding.

Note: SILICONE REMOVER (sold separately) easily removes old silicone denture liner from the acrylic denture base.

CLINICAL APPLICATION OF SOFRELINER TOUGH S LABORATORY LINING METHOD**1. Examination of mouth**

Check intraoral 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 when the new material is ground down according to the procedure in step 4, a newly lined layer of hard 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 ridge 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 borders of 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 oil-free air.

Note: Use of a round bur makes it easy to remove a uniform depth of resin. The diameter of the bur can be used 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 drip-cup. Replace the cap, closing the bottle tight 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 undisturbed for 20 minutes or more at room temperature (23°C / 73.4°F).

Note: If the set 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), by applying light pressure not to exceed 8,000 rpm.

Note: Rotate both the COARSE POINT and the FINISHING WHEEL from lined area to the denture area so as not to break the margin region (See Figure 4).

Use DIAMOND ROUND BUR (sold separately) or any suitable tool for relief.

PATIENT PRECAUTIONS

Patients should be informed of the following instructions to enhance the longevity, durability and safety of a denture lined with SOFRELINER TOUGH S:

- SOFRELINER TOUGH S lining material should not be scrubbed with a denture brush or toothbrush. The best way to clean SOFRELINER TOUGH S is with a sponge or a soft piece of gauze. While running cold water on the SOFRELINER TOUGH S surface, wipe the surface with sponge or gauze saturated with soap. Use a gentle wiping motion to remove all debris and food deposits from the SOFRELINER TOUGH S lining material. The tooth surface and hard acrylic denture base may be cleaned with a regular denture brush by scrubbing with soap, denture toothpaste or regular denture cleaners at the dentist's discretion.
- Soak the denture at least once a day, preferably at bedtime, in an oxygenating denture cleaner (i.e. Polident, Effident, etc.). The denture should not be cleaned with an oxygenating cleaner within the patient's mouth. Color fading may occur with long term use, depending upon the patient's denture maintenance. Use a denture cleaner according to its manufacturer instructions.

- Soaking the denture in heavy bleach cleaning : TOUGH S, but it will not affect its performance
- The denture should be stored in water when not
- The lined denture should be inspected and ultras whenever plaque deposit is noted.
- The SOFRELINER TOUGH S must be inspe disturbed, broken, cracked, loose or damaged lin denture could result in choking, aspiration, asphy
- In the event of any sign of sensitivity to silicone patient should contact his/her dentist immediatel

IMPORTANT NOTE: The manufacturer of SOFRE injury caused by improper use of this product. It is this product is suitable for an appropriate applica Product specifications of SOFRELINER TOUGH S the product specifications change, the instruction an

FRANÇAIS**Lire soigneusement toutes les instructions avant d DESCRIPTION DU PRODUIT ET INF**

- SOFRELINER TOUGH S est un silicone sou dentaires au fauteuil. SOFRELINER TOUGH S de revêtement souple pour prothèses dentaires P norme ISO 10139-1 « Matériaux de revêtement pour usage à court terme ».
- Le kit SOFRELINER TOUGH S contient de l accessoires tels que canules de mélange, com (noire, COARSE POINT), roue de finition (mar
- Le primaire [PRIMER] n'est utilisé que pour le être utilisé pour le collage sur des surfaces en n conditionnée dans une cartouche auto-mélange en 20 minutes à température ambiante (23°C / 73

INDICATIONS

- Douleurs causées par des crêtes saillantes de l'os
- Mauvaise rétention provoquée par une atrophie e
- Contre-dépouilles majeures ou tori maxillaire/m
- Rétention des prothèses avant la mise en place d
- Rebasage temporaire ou conditionnement des tis

CONTRE-INDICATIONS

SOFRELINER TOUGH S est contre-indiqué ch composants du silicone et du platine. Il NE faut PA

PRÉCAUTIONS

- SOFRELINER TOUGH S est prévu pour être v des soins dentaires. Il n'est pas prévu pour être v
- N'utiliser SOFRELINER TOUGH S que selon le utiliser SOFRELINER TOUGH S pour une appl
- NE PAS utiliser SOFRELINER TOUGH S si le intact.
- Le primaire [PRIMER] contient de l'éthylacétate pas exposer le primaire à une flamme nue. Utili le capuchon après utilisation.
- Si le patient a une réaction allergique au SOI contact, enlever la prothèse et en interrompre im
- Porter des gants d'examen sans latex pendant to S afin de prévenir les réactions allergiques, durcissement de SOFRELINER TOUGH S. contact avec les gants d'examen, jeter immédiat à l'eau.
- Éviter tout contact avec les yeux. En cas de con immédiatement un médecin.
- Éviter de mettre en contact avec la peau le pr avec la peau, nettoyer la zone touchée en la frott
- Éviter de mettre en contact avec les vêtements avec les vêtements, ne pas essuyer le matériau.
- NE PAS laisser du matériau excédentaire couler SOFRELINER TOUGH S aspirée ou ingérée. Enlever immédiatement de la région palatine t que le matériau ne coule dans la gorge du patie rayons X : si du matériau est aspiré ou ingéré, i cas de patient âgé dont les réflexes sont amoindr au patient de respirer par le nez pour éviter toute
- NE PAS mélanger SOFRELINER TOUGH S : instructions.
- Après avoir utilisé la cartouche SOFRELINER par le capuchon qui est fourni avec la cartouch propre avant chaque utilisation d'une canule de n
- Toujours nettoyer la spatule, les brosses et les prévenir une contamination croisée.
- Informez le patient des PRÉCAUTIONS à prend
- Pour éviter d'inhaler de la poussière pendant le j aux réglementations nationales et/ou locales.
- Lire et suivre les instructions des fabricants de t ne font pas partie du kit.
- Autant que possible, éviter tout contact avec les de rebasage. Dire aux patients de bien se rincer
- Ne pas mettre le primaire [PRIMER] en conta types de plastique.

REMARQUES CONCERNANT L'UTI

- En cas de prothèse mal fixée, rebaser d'abor acrylique, par exemple TOKUYAMA REBASE prothèses dentaires au fauteuil ou toute autre p fixation.
- En cas d'ancienne prothèse usée, rebaser d'ab matériau acrylique car les éléments absorbés p réduisent l'adhérence de SOFRELINER TOUGH
- Si la consistance du primaire SOFRELINER T l'utiliser, cela pourrait réduire sa force d'adhési
- Concernant la brosse pour le primaire, essuyer l d'alcool après chaque utilisation. Une brosse s TOUGH S.
- Ne pas mélanger les pâtes à la main car cela entraînant une détérioration, des taches et une oc
- Éviter tout contact de SOFRELINER TOUGH empêcher le durcissement de SOFRELINER TO matériaux à empreinte à base de silicone, maté au polysulfure, gants en caoutchouc naturel, m résines acryliques non durcies.
- Le matériau durcit en 5 minutes en bouche o 73.4°F). Le durcissement est achevé 24 heures : réalisée immédiatement après retrait de la prothé
- L'immersion de la prothèse dans des solutions teinte de SOFRELINER TOUGH S mais elle est
- Donner au patient des consignes de nettoyage d DE PRÉCAUTION A L'ATTENTION DES PAT
- Le matériau de test à base de silicone (fit chev donc d'appliquer de la vaseline sur la surface av
- En présence d'une fracture dans le rebasage fini, procédure.
- Se reporter aux outils suivants pour le modelage

| Étapes | Matéri |
|---|--|
| Ébarbage | Scalpel aiguisé |
| Modelage | Pointe de modelage (POINTE) |
| Finition | Roue de finition (ma WHEEL) |
| Ajustement de la surface interne (relief) | Fraise ronde en diamant DIAMOND ROUND BU |

