

**Carefully read all of these instructions before using CHAIRSIDE® Soft Reline Material.**

**■PRODUCT DESCRIPTION AND GENERAL INFORMATION**

1. CHAIRSIDE® Soft Reline Material is an addition-cured silicone chairside soft lining material for removable dentures. CHAIRSIDE® Soft Reline Material 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”.
2. CHAIRSIDE® Soft Reline Material Kit contains PASTE, PRIMER and other accessories such as mixing tips, drip nozzle, drip cup, brushes, 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 silicone surfaces. PASTE is dispensed in automix cartridge delivery system. The material sets in 5 minutes intraorally 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 ridge atrophy.
3. Major undercuts or maxillary / mandibular tori.
4. Retention of overdentures before the final attachment is placed.
5. Temporary lining or tissue conditioning.

**■CONTRAINDICATIONS**

CHAIRSIDE® Soft Reline Material is contraindicated in patients allergic to or hypersensitive to silicone and platinum compounds and should NOT be used on such patients.

**■PRECAUTIONS**

1. CHAIRSIDE® Soft Reline Material 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.
2. Use CHAIRSIDE® Soft Reline Material only as instructed herein. DO NOT use CHAIRSIDE® Soft Reline Material for any application other than those noted in these instructions.
3. DO NOT use CHAIRSIDE® Soft Reline Material if the safety seal is broken or if it appears the contents have been 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 CHAIRSIDE® Soft Reline Material, such as a dermatitis outbreak, remove the prosthesis and discontinue its use immediately.
6. Wear non-latex examination gloves at all times while using CHAIRSIDE® Soft Reline Material to avoid the possibility of allergic reactions. Latex gloves may also inhibit the setting of CHAIRSIDE® Soft Reline Material. If CHAIRSIDE® Soft Reline Material 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 materials 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 CHAIRSIDE® Soft Reline Material 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. CHAIRSIDE® Soft Reline Material 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.
11. DO NOT mix CHAIRSIDE® Soft Reline Material with any materials not noted in these instructions.
12. After using CHAIRSIDE® Soft Reline Material 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.
13. Always clean the spatula, brushes and cups with alcohol after each use to avoid cross contamination.
14. Instruct patients in accordance with the PATIENT PRECAUTIONS contained in the last section of these instructions.

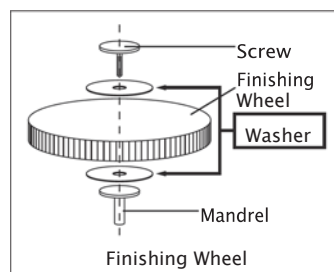


15. To avoid inhaling dust while finishing, always wear a mask recommended by federal and/or local regulations.
16. Read and follow the manufacturers' instructions for all products mentioned in this instruction manual that are not included in this kit.
17. As much as possible, avoid contact of CHAIRSIDE® Soft Reline Material 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 place 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 hard denture lining material, or any other laboratory/indirect procedures to improve the fit.
2. In the case of an old worn denture, the surface to be lined should first be lined with new acrylic material since the materials absorbed in the old worn resin such as oil or water lowers the adhesion of CHAIRSIDE® Soft Reline Material.
3. If the CHAIRSIDE® Soft Reline Material 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 alcohol-soaked cotton swab or gauze after each use. Contaminated brush can lower the adhesion of CHAIRSIDE® Soft Reline Material.
5. 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.
6. Avoid contact CHAIRSIDE® Soft Reline Material with the materials below, as they may inhibit the setting of CHAIRSIDE® Soft Reline Material: Silicone-based impression materials, eugenol containing materials, polysulfide rubber impression materials, natural rubber gloves, other manufacturer's soft lining materials and uncured acrylic resins.
7. 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.
8. Soaking the denture in solutions containing heavy bleach may alter the color of CHAIRSIDE® Soft Reline Material; however, it will not affect its performance.
9. Instruct patient to clean the denture as described in PATIENT PRECAUTIONS.
10. Since silicone-based fit checking material sticks to CHAIRSIDE® Soft Reline Material, apply Vaseline on the surface prior to use.
11. If there is a fracture in the finished liner, completely remove the liner and repeat the procedure.
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



#### ■STORAGE

1. Store CHAIRSIDE® Soft Reline Material at a temperature between 0 – 25 °C (32 – 77°F).
2. Avoid direct exposure of CHAIRSIDE® Soft Reline Material to heat, open flame, humidity and sunlight.
3. Do not use CHAIRSIDE® Soft Reline Material after the indicated date of expiration.
4. DO NOT leave CHAIRSIDE® Soft Reline Material 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 gauze or cotton, and disposed of in accordance with local regulations.

## ■CLINICAL APPLICATION OF CHAIRSIDE® Soft Reline Material INTRAORAL LINING METHOD

In most cases the optimum thickness of CHAIRSIDE® Soft Reline Material should be 1-2 millimeter. If a thickness of over 2 millimeters is required, the area should first be lined with hard denture lining material 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).

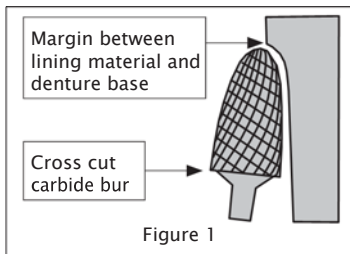


Figure 1

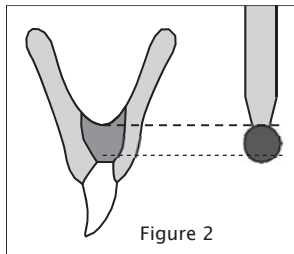


Figure 2

### 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 CHAIRSIDE® Soft Reline Material 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 CHAIRSIDE® Soft Reline Material PASTE cartridge into a dispensing gun (DS-50 1:1/2:1 (for 50ml cartridge, 1:1/2:1 ratio plunger)). 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 CHAIRSIDE® Soft Reline Material, 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 CHAIRSIDE® Soft Reline Material in the patient's mouth, and remove immediately if present. Advise patients to alert the dentist immediately if he/she feels CHAIRSIDE® Soft Reline Material or any substance flowing toward the throat.

Note: To line upper denture with CHAIRSIDE® Soft Reline Material, insert the denture from the posterior palatal region to avoid flow of CHAIRSIDE® Soft Reline 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

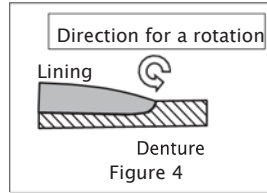
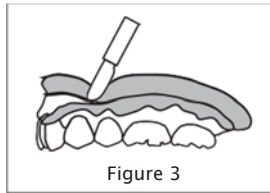
Pull the cheeks very gently to mold the border of vestibule area while the patient is gently occluding. If patient salivates, suction the saliva and instruct the patient to resume occluding gently. CHAIRSIDE® Soft Reline Material should be allowed to set intraorally for at least 5 minutes.

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 CHAIRSIDE® Soft Reline 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).

## 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 CHAIRSIDE® Soft Reline Material by cutting it off with a sharp instrument. Remove the remaining material by grinding.

## ■ CLINICAL APPLICATION OF CHAIRSIDE® Soft Reline Material 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 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 CHAIRSIDE® Soft Reline Material 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 the denture 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 CHAIRSIDE® Soft Reline Material 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 CHAIRSIDE® Soft Reline Material PASTE cartridge into a dispensing gun (DS-50 1:1/2:1 (for 50mL cartridge, 1:1/2:1 ratio plunger)). 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 CHAIRSIDE® Soft Reline 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).

### **■ PATIENT PRECAUTIONS**

Patients should be informed of the following instructions to enhance the longevity, durability and safety of a denture lined with CHAIRSIDE® Soft Reline Material:

1. CHAIRSIDE® Soft Reline Material should not be scrubbed with a denture brush or toothbrush. The best way to clean CHAIRSIDE® Soft Reline Material is with a sponge or a soft piece of gauze. While running cold water on the CHAIRSIDE® Soft Reline Material 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 CHAIRSIDE® Soft Reline 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.
2. Soak the denture at least once a day, preferably at bedtime, in an oxygenating denture cleaner (i.e. Polident, Efferdent, 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.
3. Soaking the denture in heavy bleach cleaning solutions may alter the color of the CHAIRSIDE® Soft Reline Material, but it will not affect its performance.
4. The denture should be stored in water when not being worn.
5. The lined denture should be inspected and ultrasonically cleaned by a dentist every three months, or whenever plaque deposit is noted.
6. The CHAIRSIDE® Soft Reline Material must be inspected frequently for any damage. A denture with disturbed, broken, cracked, loose or damaged liner should not be worn. Use of a damaged or broken denture could result in choking, aspiration, asphyxiation or other injury.
7. In the event of any sign of sensitivity to silicone, use of the denture should be discontinued, and the patient should contact his/her dentist immediately.

CAUTION: Federal law restricts this device to sale by or on the order of a dental professional.

IMPORTANT NOTE: The manufacturer of CHAIRSIDE® Soft Reline Material is not responsible for damage or injury caused by improper use of this product. It is the personal responsibility of the user to ensure that this product is suitable for an appropriate application before use.

Product specifications of CHAIRSIDE® Soft Reline Material are subjected to change without notification. When the product specifications change, the instruction and precaution may change also.

