

CAUTION: US Federal Law restricts this device to use or sale by order of a licensed professional.

## Mucosoft®

### Instructions for use

**Not for relining nylon-based “flexible” denture materials, e.g., Flexite®, Valplast®, etc.**

**Store in refrigerator for longest shelf life. Use at room temperature for best results.**

#### DESCRIPTION:

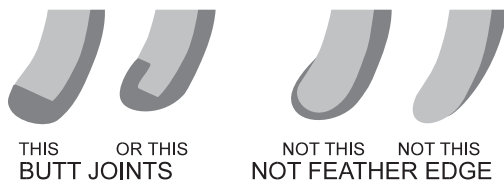
Mucosoft® is an easy-to-apply, chairside, self-curing silicone for use as a long-term soft lining material. It is taste-free, odorless, and translucent pink to complement the shade of an existing full or partial denture base.

#### INDICATIONS:

Mucosoft® is recommended for use where retentive undercuts in edentulous ridges cause patient discomfort; where bony projections from edentulous ridges create recurring sore spots and tissue tenderness; where denture-supporting soft tissues are tender and hard denture bases cause patient discomfort, or wherever a patient might benefit from the cushioning effect of a soft silicone liner.

#### DIRECTIONS:

- 1) Confirm that soft tissue is healthy and free of fungal or other irritations before attempting a reline.
- 2) Thoroughly disinfect, wash and dry prosthesis to be relined. With a suitable acrylic bur, remove at least 1mm of hard denture base from the tissue side of the appliance. **To provide adequate space and avoid debonding or material failure, it is important to create a minimum of 1mm of relief. Anywhere from 1-3mm is suggested.**
- 3) The periphery of the appliance should also be trimmed and beveled to permit at least 2mm of Mucosoft® to roll over the denture’s borders.



**Cut the acrylic border so it will form a butt-joint with the reline material. Feather-edge joints will encourage debonding.**

- 4) Dispense Mucosoft® Bonding Liner into a dappen dish. Using a disposable brush, apply a thin, even layer onto all prepared, dry surfaces of the denture and let it air dry for about 2 minutes. **Do not apply to soft tissues. Only use Bonding Liner extra-orally in well-ventilated areas.**

- 5) Remove sealing cap from Mucosoft® cartridge and discard. **Before affixing a mixing tip, dispense about 1/4 inch of base and catalyst onto a pad to make certain both openings of the cartridge are clear and that material flows freely and equally from both of them.** Attach a mixing tip and express auto-mixed Mucosoft® silicone across the entire adhesive-treated area. To minimize air bubbles, it is suggested that you start at the posterior border, and fill the denture with a continuous overlapping, back-and-forth pattern (somewhat like mowing a lawn). Use progressively smaller semi-circles following the denture arch (see diagram right). If necessary, a cement spatula (or similar) may be used to spread the silicone more evenly over denture surfaces. **Be sure to cover all adhesive-treated areas with silicone. Avoid latex glove contamination that can interfere with the silicone setting reaction.** Never substitute a silicone impression material for Mucosoft® Soft Reline Silicone. Leave used mixing tip in place as cartridge-sealer between uses.

- 5) Have the patient rinse with mouthwash to reduce excess saliva before seating the appliance. **When inserting the silicone-filled appliance, it's best to seat from posterior to anterior with a rolling motion that avoids air entrapment and directs excess material away from the throat.** Confirm proper seating of the appliance and remove any excess material.

- 6) Guide the patient into centric at proper vertical. Manipulate cheeks to border mold the material. Have the patient hold in centric occlusion until silicone has completely set (at least 5 minutes in the mouth). Excess material may be removed during this period. Keep a constant check on and evacuate excess saliva. Have patient return to centric occlusion after any evacuation.

- 7) Remove the appliance and carefully trim away excess silicone with scissors, a sharp scalpel, a single-edge razor blade or suitable burs or trimmers. Avoid leaving any loose silicone material on the denture. **Do not over-trim at the silicone/acrylic margins.**

- 8) Mix equal parts of A and B Mucosoft® Glaze and apply mixture to the cut surfaces of the reline with a disposable brush. Allow it to set completely, about 2 to 3 minutes @ room temperature followed by at least 1 minute in hot water, to impart a smooth, polished finish. **Do not disturb the glaze before complete set.**

#### CONTRAINDICATIONS:

Not for use on or by individuals who are sensitive to silicone products.

**Mucosoft® Glaze is not intended to smooth rough edges and surfaces. This should be accomplished with suitable instruments before glazing.**

#### WARNINGS:

**Not for internal use. Avoid swallowing. Although non-toxic, aspirated silicone materials can be harmful. Avoid contact with eyes. Seek medical advice if either should occur.**

**If signs of silicone sensitivity should develop, use of the Mucosoft® relined appliance should be discontinued.**

#### PRECAUTIONS:

Soaking in strong bleach may fade or discolor the reline. However, patient must be warned of the critical importance of maintaining cleanliness of appliance to prevent fungal contamination. Bleach and vinegar soaks are not indicated.

**See patient information handouts enclosed.**

If a Mucosoft® reline shows signs of separating, cracking, loosening or other damage, it should not be worn. Repair should be made at the earliest to avoid aspirating fragments of silicone.

#### REPAIRS:

Silicone reline materials will not adhere to each other. If a repair is needed, the entire soft reline must be replaced.

#### SUPPLIED AS:

- 1 x 50ml standard (1:1) cartridge + mixing tips
- 1 x 15ml bonding liner + dispensing pipettes
- 1 x 6 ml A + 6ml B glaze (total 12ml)
- Disposable applicator brushes for bonding liner and/or glaze

#### WARRANTY:

Parkell will replace defective material. **This warranty is in lieu of all warranties of merchantability, fitness for purpose or other warranties, express or implied.** Parkell does not accept liability for any loss or damage, direct, consequential or otherwise, arising out of the use of or the inability to use the product herein described.

Before using, the user shall determine the suitability of the product for its intended use and the user assumes all risk and liability whatsoever in connection herewith.

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