



parkell S491S MucoSoft Denture Reline Material Instructions

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MucoSoft Denture Reline Material Instructions for Use

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S491S MucoSoft Denture Reline Material



Store at room temperature with a clean cap tightly locked on. Avoid freezing. Do not store near excessive heat, light, or fresh eugenol-containing materials.

IMPORTANT NOTE: Not for relining nylon-based “lexible” denture materials, e.g., Flexite®, Valplast®, etc.

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 for Use:

A soft reline material for use by trained dental professionals. The material is a self-polymerizing material that is used to reline the tissue contacting resin surfaces of removable prostheses, either full or partial, to enhance the comfort and it of said removable prosthetic appliances.



Precautions:

- Patient must be warned of the critical importance of maintaining cleanliness of appliance to prevent fungal contamination. Bleach soaks are not indicated.
- If a Mucosoft reline shows signs of separating, cracking, loosening or other damage, it should not be worn. Repair should be made as soon as possible to avoid aspirating fragments of silicone.

MucoSoft Kit Contains:

- (1) 50ml cartridge of MucoSoft Reline Silicone
- (1) 15ml MucoSoft Bonding Liner Adhesive
- 12ml Glaze; (2) components A&B
- (6) Mixing tips
- Brushes and pipettes
- Instructions for Use

Directions for Use and Clinical Tips:

	
<p style="text-align: center;">This – or – This Butt Joints</p>	<p style="text-align: center;">NOT This – or – NOT This NOT Feather Edge</p>

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

1. With a suitable acrylic bur, remove at least 1 mm 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 1 mm of relief. Anywhere from 1-3 mm is suggested.
2. The periphery of the appliance should also be shortened to permit at least 2 mm of Mucosoft to roll over the denture's borders.
3. Using the pipette, 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. Only use uBonding Liner extra-orally in well-ventilated areas.

WARNING: Bonding Liner contains methylene chloride. Use caution after carefully consulting the Safety Data Sheet (SDS).

4. Remove sealing cap from Mucosoft cartridge and discard. Before a mixing tip, dispense about 1/4 inch of base and catalyst onto a pad to make certain that material flows freely and equally from both openings. Attach a mixing tip and express auto-mixed Mucosoft 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. If necessary, a cement spatula (or similar) may be used to spread the silicone more evenly over the borders. Be sure to cover all adhesive-treated areas with silicone.

Avoid latex glove contamination that can interfere with the silicone setting reaction. 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, use appropriate technique to avoid air entrapment and direct 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 until silicone has completely set (at least 5 minutes in the mouth). If necessary the patient may open to allow removal of excess material or evacuation, but should return to centric afterward.
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 at 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.

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.

Not for use on or by individuals who are sensitive to silicone products. If signs of silicone sensitivity should develop, use of the Mucosoft relined appliance should be discontinued.

Repairs:

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

Tips for Dental Practitioners for Cross-Contamination Control:

The following information should help dental practitioners reduce the risk of cross-contamination between patients when using multiple-use dental dispensers: apply disposable barrier sleeves/wraps over multiple-use dental dispensers before use with each patient; use new, uncontaminated gloves when handling multiple-use dental dispensers; utilize dental assistants to dispense material for the dentist when appropriate; avoid contact of the reusable parts (e.g., the body of the multiple-use dental dispenser) with the patient's mouth; do not reuse the multiple-use dental dispenser if it becomes contaminated; do not immerse multiple-use dental dispensers in a high level chemical disinfectant, as this may damage the dispenser and the material contained in the device; do not sterilize multiple-use dental dispensers, as this may damage the material contained in the device.

The cartridge and dispensing gun can be cleaned of debris with an EPA-registered low-level to intermediate-level hospital disinfectant.

The used mixing tip should be discarded, and the original cap should be reattached to the cartridge to re-seal until next use. Utilize the surface disinfecting protocol of the disinfectant manufacturer. Consult www.CDC.gov for the most recent version of the "Guidelines for Infection Control in Dental Health-Care Settings".

Disposal of Material:

Before disposal, the product should be fully mixed with the mixing tip, cured and then discarded in the general refuse. All cartridges and mixing tips may be disposed of in normal refuse.
















Events:







Reportable incidences should be reported to Parkell and the competent authority in which the user and or patient is established.

Warranty and Terms of Use:

For full Warranty and Terms of Use information, please see www.parkell.com. Safety Data Sheets (SDS) are available at www.parkell.com. Parkell's Quality System is certified to ISO 13485.

Explanation of Symbols Used:

	<ul style="list-style-type: none">• Professional use only
	<ul style="list-style-type: none">• Follow instructions for use
	<ul style="list-style-type: none">• Temperature limit
	<ul style="list-style-type: none">• Store product tightly sealed away from direct sunlight.
	<ul style="list-style-type: none">• Use-by date (expiration)
	<ul style="list-style-type: none">• Batch code
	<ul style="list-style-type: none">• Catalogue / stock number
	<ul style="list-style-type: none">• Caution
	<ul style="list-style-type: none">• Flammable
	<ul style="list-style-type: none">• Serious health hazards
	<ul style="list-style-type: none">• Package contents
	<ul style="list-style-type: none">• Unique Device Identifier
	<ul style="list-style-type: none">• Medical Device
	<ul style="list-style-type: none">• Do not use if package is damaged
	<ul style="list-style-type: none">• Single use only

	<ul style="list-style-type: none"> • Manufacturer
	<ul style="list-style-type: none"> • 15 ml liquid
	<ul style="list-style-type: none"> • 50ml Split Cartridge / paste
	<ul style="list-style-type: none"> • Mixing Tip
	<ul style="list-style-type: none"> • Applicator brush
	<ul style="list-style-type: none"> • Dispensing pipette



S491S, S492S, S493, S494

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Rx Only—product is intended for use by a licensed dental professional.

For Safety Data Sheet (SDS) go to www.parkell.com

MADE IN USA

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Documents / Resources

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References

- [CDC Centers for Disease Control and Prevention](#)
- [Dental Tools, Devices and Materials](#)