

INSTRUCTIONS FOR USE



MucoHard™

DENTURE RELINE MATERIAL (REF S487)

A00516revM0721

IMPORTANT NOTE:

CLINICIANS SHOULD READ AND UNDERSTAND THE SPECIAL PRECAUTIONS NECESSARY TO PROTECT THE PATIENT FROM HEAT GENERATED DURING CURING OF MUCOHARD.

Store in a refrigerator with cap or used mixing tip tightly screwed on. Avoid freezing. Allow chilled material to come to room temperature before use. Cold material may be difficult to express, and take longer to cure. Avoid storing near excessive heat, light or fresh eugenol-containing materials.

DESCRIPTION:

Parkell's MucoHARD™ is a self-cured, pink gingival-colored, hard-setting resin packaged in an auto-mix cartridge that is more convenient and faster to use than powder/liquid systems. The MucoHARD kit includes an adhesive bonding liquid that enhances the bond to underlying acrylics and extends the life of the reline. After polymerization, MucoHARD may be trimmed and polished with conventional laboratory carbide burs.

INDICATIONS FOR USE:

MucoHARD is indicated for making hard relines, repairs or additions to full or partial acrylic dentures.

CONTRAINDICATIONS AND PRECAUTIONS:

- MucoHARD should not be used on or by persons who are allergic or sensitive to methacrylate-based resins. Symptoms may include dermatitis or inflammatory reactions. Keep these materials away from children.
- Uncured MucoHARD is not for internal use and should not be swallowed, or contact eyes or mucous membranes other than the intraoral tissues. If necessary, flush with copious water, discontinue use and obtain medical care.
- **MucoHARD products generate significant heat while setting. The amount and timing of this heat depends on the volume of material. Do not leave the patient alone while MucoHARD products are setting in the mouth. Be prepared to IMMEDIATELY**

remove the prosthesis from the mouth when the patient senses the rising heat. Do not let MucoHARD cure to completion in the mouth. Final set should be "on the bench".

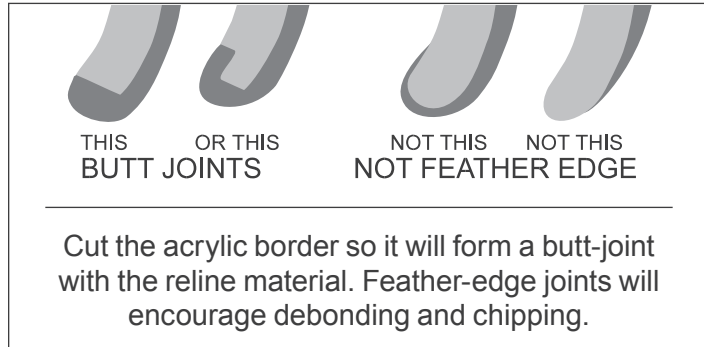
- MucoHARD is not for use on flexible nylon-based materials such as Flexite® or Valplast®.
- The MucoHARD adhesive bonding liquid can damage clothes, countertops, flooring, carpets, etc. Take care that the liquid does not accidentally contact these items.
- To avoid lock-on when relining a denture, block out any undercuts with appropriate material.
- Shelf life will be reduced if not stored properly. After initial use, store in a cool, dark place with used mixing tip tightly screwed on. Do not replace mixing tip until ready for next use, and do not re-use the original cap.
- Excessive or intense squeezing force on cartridge-based restorative materials may cause gun breakage or cartridge cracking. Slow and steady force is preferred for dispensing these materials.
- Stated work times and set times are estimates and may vary based upon storage condition, temperature, humidity, age of product, when the cartridge was first opened, among other factors.

THE MUCOHARD KIT CONTAINS:

- (1) 50ml automix cartridge of MucoHARD Reline Resin (refill REF S486) for use with a DS-50 1:1/2:1 Automix Gun (REF S343 available separately from Parkell).
- (1) 15ml bottle of MucoHARD Adhesive Bonding Liquid (refill REF S485)

- Large diameter mixing tips with blue-green base (refill [REF S496](#))
- Applicator brushes and dispensing pipettes
- Instructions for Use and Patient Information Sheets.

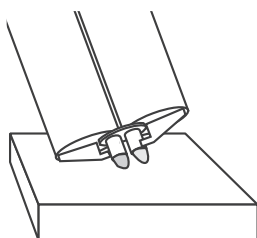
DIRECTIONS FOR USE AND CLINICAL HINTS:



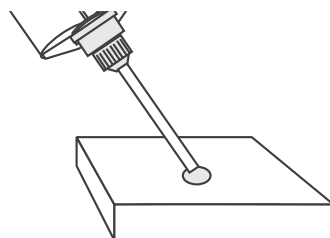
1. Clean and disinfect the existing acrylic denture.
2. With appropriate rotary instruments, remove 1-2 mm of existing acrylic denture base from the surface to be relined. For best peripheral bond, remove at least 1 mm of border and create a butt joint (not a feather edge) between the new and old material. Wash and thoroughly dry the prosthesis before proceeding to next step.
3. Using a disposable pipette, transfer 2-3ml of Adhesive Bonding Liquid into a dappen dish or similar container. Using a disposable brush, brush a generous amount of the liquid into an even layer on the inner surface ("intaglio") of the denture. Allow the liquid to evaporate undisturbed on the acrylic for at least 2 minutes. The liquid evaporates quickly, so immediately recap the bottle after use.

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

4. **DOUBLE-BLEED THE CARTRIDGE:** Place the MucoHARD cartridge into any impression gun marked "DS-50/1:1, 2:1" Remove and discard the shipping cap and bleed a small amount of material onto a pad to assure that both barrels are flowing through the round orifices (Figure 1). Affix a blue-



(Fig. 1) First Bleed



(Fig. 2) Second Bleed

green mixing tip to the cartridge and express a small, pea-size amount of MucoHARD through the tip and onto a pad (Figure 2).

5. Immediately express the material into the denture intaglio and spread it out evenly with a spatula. Roll the material over all the borders. To avoid having the material flow down the patient's throat, do not overload the denture. Leave the mixing tip on the cartridge to seal out air and serve as the new cap.
6. Position the patient in an upright position and insert the denture into the mouth from front to back, to avoid trapping air on the palate. Gently pull out the lips and cheeks to avoid trapping them under the borders. Guide the patient into desired centric at the proper vertical dimension and muscle-trim the borders using standard methods. **DO NOT LEAVE THE PATIENT ALONE WHILE THE MATERIAL SETS.**
7. **Remove the denture at the first sign that the patient is feeling a noticeable elevation in temperature in the mouth from the setting material. Because of varying intra-oral and room temperatures, you cannot rely on timers for this removal sign, but it will generally occur in 2-3 minutes as measured from when the material is expressed from the cartridge. IT IS IMPORTANT THAT THE PATIENT IS CLOSELY MONITORED AT THIS POINT AS DISCOMFORT OR EVEN INJURY CAN RESULT FROM OVER-EXPOSURE.**

NOTE: To reduce the aftertaste from the MucoHARD after removing the denture from the patient's mouth, wipe the oral tissues with a 2x2 gauze pad dampened with a flavored mouthwash. Afterward, have the patient rinse their mouth with mouthwash as well.

8. Allow the denture reline to harden outside the mouth for at least 3 additional minutes.

NOTE: Small voids in the reline can be filled immediately after the resin has set, but before removal of the air-inhibited layer. Repeat the above steps, syringe additional small amounts of MucoHARD into the voids, and reseal the prosthesis in the mouth until set begins as above.

9. Remove the air-inhibited layer from the denture by scrubbing it with a toothbrush and an alcohol-containing mouthwash. Trim, polish and rinse the denture, and deliver it to the patient with instructions for home care.
10. The cartridge, used mixing tip and dispensing gun should not be directly sprayed with or soaked in disinfectant. They can be cleaned of debris with a damp paper towel, disinfected by wiping with a paper towel that has been saturated with an EPA-registered low-level (HIV/HBV claim) to intermediate-level (tuberculocidal claim) hospital disinfectant, wiped of chemical

residue with a water-damp paper towel, and dried. 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”.

11. Leave the used mixing tip in place on the cartridge to seal out air between uses. Do not re-use the shipping cap.




















TIPS FOR DENTAL PRACTITIONERS FOR CROSS-CONTAMINATION CONTROL:

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; 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 reprocess a contaminated multiple-use dental dispenser by using chemical wipes or disinfectants; 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.

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

	Professional use only
	Follow instructions for use
	Temperature limit
	Store product tightly sealed away from direct sunlight.
	Use-by date (expiration)
	Batch code
	Catalogue / stock number
	Package contents
	Flammable
	Health hazard
	Serious health hazard
	Do not use if package is damaged
	Single use only
	Manufacturer
	50 ml Split Cartridge / Paste
	Pipette
	Mixing Tip
	Applicator Brush
	15 ml bottle / liquid

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