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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

MucoHard+™

Denture Reline Material

Instructions for Use

REF S640, S641, S642

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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.

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. MucoHard+ is biocompatible, tasteless, odorless, esthetic, MMA-free, and has a low exothermic temperature for patient comfort during the initial intraoral self-curing stage. The MucoHard+ kit includes an adhesive bonding liquid that enhances the bond to underlying acrylics and extends the life of the relines.

Indications for Use:

MucoHard+ is indicated for hard relines, repairs and for additions to full or partial acrylic dentures.

Contraindications:

- 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+ should not be used on anesthetized or sedated patients.
- MucoHard+ should not be used as a pick-up material for implant or natural teeth attachment components.
- MucoHard+ is not for use on flexible nylon-based materials such as Flexite® or Valplast®.

Precautions:

- MucoHard+ may generate a modest level of heat while curing intraorally which the patient may identify as either an increase in temperature or as a tingling sensation. The amount of heat or tingling, and the onset of either of these sensations, can vary from patient to patient. Prior to the MucoHard+ relines being placed in the patient's mouth, the dentist and the patient should discuss the possibility of onset of such heat or tingling, and the patient should be instructed to immediately inform the dentist if and when they experience such heat or tingling, whereupon the dentist should immediately remove the denture from the patient's mouth.
- The MucoHard+ adhesive bonding liquid can damage clothes, countertops, flooring, carpets, etc.
- To avoid lock-on when relining a full denture, block out any undercuts. When relining partials, block out any clasps with an appropriate material.

- Shelf life will be reduced if not stored properly. After initial use, store in a cool, dark place with the original cap tightly screwed on.
- Excessive or intense squeezing force on cartridge-based restorative materials may cause gun breakage or cartridge cracking.
- Any stated work times and set times are estimates. Factors that can influence work/ set times include, but are not limited to, storage condition, temperature, humidity, age of product, and/or when the cartridge was first opened.

MucoHard+ Kit Contains:

- (1) 50 ml automix cartridge of MucoHard+ Reline Resin (refill REF S641)
- (1) 15 ml bottle of MucoHard+ Adhesive Bonding Liquid (refill REF S642)
- Large diameter mixing tips with blue-green base (refill REF S496)
- Applicator brushes (refill REF S495)
- Instructions for Use

Directions for Use and Clinical Tips:

This – or – This Butt Joints	NOT This – or – NOT This NOT Feather Edge
Cut the acrylic border so it will form a butt-joint with the relines material. Feather-edge joints will encourage debonding and chipping.	

1. Clean and disinfect the existing acrylic denture.
2. Remove 1-2 mm of the existing acrylic denture base from the surface to be relined. For best peripheral bond, remove at least 1 mm of the border and create a butt joint (not a feather edge) between the new and old material. Rinse and thoroughly dry the prosthesis.
3. Transfer 2-3 ml of Adhesive Bonding Liquid with a disposable pipette into a dappen dish or similar container and immediately recap the adhesive liquid bottle to prevent evaporation. Apply a generous amount of the Bonding Liquid evenly on the inner surface ("intaglio") of the denture with a disposable brush. Wait at least 2 minutes for the liquid to evaporate from the denture surface.

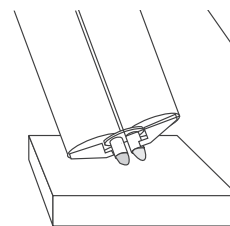


Fig. 1: First bleed

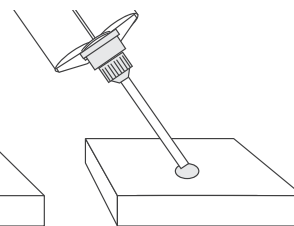


Fig. 2: Second bleed

4. **DOUBLE-BLEED THE CARTRIDGE:** Place the MucoHard+ cartridge into any impression gun marked "DS-50/1:1, 2:1" Remove the shipping cap, but do not discard as you will be using it later to recap and reseal the cartridge. Bleed a small amount of material onto a pad to assure that material is coming out of the orifices of both barrels (**Figure 1**). Affix a blue-green mixing tip to the cartridge and express a small amount of MucoHard+ through the tip onto the pad (**Figure 2**). Immediately after this second bleed, continue to express the material into the denture intaglio and spread evenly. Roll the material over all the borders. The chemical curing reaction begins immediately upon dispensing during the second bleed. Therefore, loading and preparing the denture for insertion into the patient's mouth should be completed 30 to 45 seconds from the start of the second bleed.

CAUTION: To avoid having the material flow down the patient's throat when relining an upper denture, do not overload the prosthesis.

5. Position the patient in an upright position. Insert the denture into the mouth and apply slight pressure to ensure complete adaptation to the tissue. While continuing to hold the denture in place, gently pull the lips and cheeks to ensure they do not get trapped under the borders. Guide the patient into desired centric at the proper vertical dimension and muscle-mold the borders.

6. While MucoHard+ is in the patient's mouth, the dentist should remind the patient to alert the dentist if they are feeling any heat or tingling sensation that is making them uncomfortable. Upon such notification, the dentist should be prepared to remove the denture immediately from the patient's mouth. **IMPORTANT NOTE: never let MucoHard+ cure to completion in the mouth; maximum time (from dispensing to removal from the mouth) must not exceed (i) approximately 3 minutes or (ii) when the patient indicates an increase in heat or tingling sensation from the relined denture, whichever occurs earlier. After removal, it will take an additional 5 minutes outside the mouth to fully cure.**

Technique Tip: Small voids in the reline can be filled immediately after the resin has fully set, but before removal of the air-inhibited layer by repeating Steps 4 – 7.

7. Remove the air-inhibited layer from the denture by scrubbing it with a toothbrush and mouthwash. Trim, adjust, and polish using burs and polishers labeled for use on hard denture acrylic.

8. Rinse the denture and deliver it to the patient with instructions for home care.

9. Wipe the original cartridge sealing cap to remove any excess material prior to placing it back onto the MucoHard+ cartridge. This will prevent possible cross-contamination of the base and catalyst.

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:

	• 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
	• Caution
	• Flammable
	• Serious health hazards
	• Package contents
	• Unique Device Identifier
	• Medical Device
	• Do not use if package is damaged
	• Single use only
	• Manufacturer
	• 15 ml liquid
	• 50ml Split Cartridge / paste
	• Mixing Tip
	• Applicator brush
	• Dispensing pipette