

Mucopren[®]

soft

Manufacturer:

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Distributed in the U.S. by:

Kettenbach LP

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Vinyl Polysiloxane Reline Material

ISO 10139-2:2009-08, Type A

Made in Germany
37172/5111



For professional use only. Caution: Federal (U.S.A.) Law restricts this device to sale by or on the order of a dentist.

Product Description

Mucopren® soft is a permanently soft durable reline material based on vinyl polysiloxane for direct and indirect application.

Indications/Techniques

Mucopren® soft can be applied directly or indirectly

- for permanently soft linings
- for compensating for areas of mucous membrane with varying degrees of resiliency
- for relieving sharp bony ridges
- for relieving the operation site after placing implants
- for relining temporary restorations
- for conditioning the mucous membranes in cases with denture sores
- for fabricating and relining obturators

Warnings

Do not use Mucopren® relining material as an impression material.

Cautions

Do not use after expiration date.

Handling instructions for relined dentures are in this sheet.

Do not leave remains of soft liner in the mouth.

Do not swallow this material! If swallowed: consult a medical doctor if problems arise or persist.

Avoid contact with eyes. If accidental contact with the eyes occurs, rinse immediately and thoroughly with an eye wash or water. Consult a medical doctor if problems arise or persist.

The product does not normally cause allergic reactions. However, for sensitive persons, an allergic reaction to the product cannot be ruled out.

Also, if used on patients whose immune system is impaired, or on those who are suffering from a variety of other diseases (such as diabetes mellitus) or those who are taking medications including antibiotics or cortisone, it has been observed in rare cases that micro organisms (e.g. candida albicans) may colonize the soft lining. In such ca-

ses, whenever the lining of the dentures is replaced, soft lining should not be used since the re-colonization by micro organisms is likely if the patient status remains unchanged.

Increased colonization by micro organisms and the development of denture stomatitis has also been observed in patients due to inadequate oral hygiene and improper cleaning of the lined dentures.

Should the silicone soft liner require adjustment, relieve the area liberally and apply another coat of Mucopren® soft. Brush two coats of adhesive onto the exposed areas of acrylic only.

If the relined restoration is not adequately maintained, it cannot be ruled out that micro organisms will settle on the surface and that denture stomatitis will develop.

When handling chemicals the usual precautions must be taken.

Do not allow the material to enter the sewer or water system to avoid environmental contamination.

Avoid contact with clothing, since the material cannot be removed by dry cleaning.

Product Overview

Product name	ISO 10139-2	Mixing ratio and total content volume per unit	Mixing technique	Mixing element
Mucopren® soft	Type A	1:1, 50 ml cartridge	Applyfix® 4 dispensing gun DS-50 1:1/2:1	static green mixing tip MB Ø 6.5 mm
Mucopren® soft Silicone sealant	—	1:1, 50 ml cartridge	Applyfix® 4 dispensing gun DS-50 1:1/2:1	static blue mixing tip MB Ø 3.2 mm
Mucopren® Adhesive	not applicable	not applicable	—	brush

Technical Data

Product name	Mixing ratio	Working time at 23 °C/ 74 °F ≤	Working time at 35 °C/ 95 °F ≤	Intraoral setting time at 35 °C/ 95 °F ≥	Total setting time ≥	Hardness (approx.) Shore	Linear dimensional change (approx.) %	Elastic-Recovery test (approx.) %	Strain in compression (approx.) %
Mucopren® soft Direct reline	1:1	2 minutes 15 seconds	not applicable	3 minutes 15 seconds	5 minutes 30 seconds*	A 28	- 0.20	99.5	9.4
Mucopren® soft Indirect reline	1:1	2 minutes 15 seconds	not applicable	not applicable	> 30 minutes in pressure vessel	A 28	- 0.20	99.5	9.4
Mucopren® soft silicone sealant	1:1	1 minute 30 seconds	not applicable	not applicable	6 minutes 30 seconds at 23 °C/74 °F	A 33	—	—	—

*Total setting time (removal time from mouth) from start of mix.

Note

To ensure optimal relinings, the temperature of the material should not deviate from 23° C (74° F) before applying. Otherwise, working and setting times will be affected. The water temperature and time in the water are critical factors in ensuring an optimum bond between Mucopren® soft and PMMA.

Please note – Mucopren® Adhesive

- Close the bottle of Mucopren® adhesive immediately after use.
- Should the contents of the bottle be spilled, it is advisable to ventilate the area and absorb the spilled adhesive with universal binding agent.
- The adhesive contains ethyl acetate.



- R 11 Highly flammable
R 36 Irritating to eyes
R 43 May cause sensitisation by skin contact
R 66 Repeated exposure may cause skin dryness or cracking
R 67 Vapours may cause drowsiness and dizziness



- S 24/25 Avoid contact with skin and eyes
S 37 Wear suitable gloves

Cartridge material for use in Applyfix® 4 dispensing gun DS-50 1:1/2:1

Insert the cartridge into the Applyfix® 4 dispensing gun DS-50 1:1/2:1. Ensure that the notches on the cartridge base are pointing down. The clasp will not close if the cartridge is not properly inserted into the dispensing gun. Remove the cartridge cap. The cap can be replaced after initial use.

Insert plunger into cartridge and dispense a small amount of reline material until equal amounts are dispensed at the same rate.

Install a mixing tip on the cartridge, and turn cap 90 degrees clockwise to lock in place.

Apply Mucopren® soft uniformly with a dispensing gun and insert it into the patient's mouth immediately. Leave used mixing tip on the cartridge after use or replace the cartridge cap.

Before using the cartridge again, remove cartridge cap or

remove and discard the used mixing tip. Check the cartridge openings to ensure no polymerized material is present. Should this be the case, unblock the openings and dispense a small amount of reline material until equal amounts are dispensed at the same rate.

Install a new mixing tip and continue as described above. The Applyfix® 4 dispensing gun DS-50 1:1/2:1 can be sterilized in the autoclave.

Instructions for use for the direct and indirect methods

Mucopren® soft was developed specifically for the use of cold and hot polymerizing denture base plastics. Wash the denture base thoroughly with water and dry it. Use a bur to reduce the surface to allow for the thickness of soft liner required. To create a neat vestibular juncture between the soft liner and denture acrylic, it is advisable to trim a right-angled periphery as shown in Figure 1.

Once the surface has been prepared and roughened, brush on a thin coat of Mucopren® Adhesive, wait 30 seconds before applying a second coat, and allow it to dry in air for at least 90 seconds. Ensure that the adhesive is applied **beyond the prepared periphery.**

Apply Mucopren® soft uniformly with a dispensing gun

(to prevent air voids being entrapped, keep the mixing tip in the material) and insert it into the patient's mouth immediately. The active and passive functional excursions can then be carried out. Processing: Once the denture has been removed from the patient's mouth, immerse the denture and soft lining in water at ≥ 50 °C/122 °F for at least 15 minutes. Dentures which are not made of standard self-curing acrylic should be immersed in lukewarm water (30 – 35 °C) for 2 hours. Once the material has cured, cut the excess material off with scissors, a scalpel or rotary instrument to create a neat juncture between the denture acrylic and soft liner (refer to Figure 2). Cross-cut steel burs for soft linings (e.g. Busch Fig. 82060) are useful for bulk reduction. Final finishing can be carried out with the polishing discs (supplied with the basic set). Trimmed areas of acrylic can be polished as usual. Do not use polishing paste that leaves residual grease. Always clean the surfaces with hot water (steam cleaner) and dry them before sealing.

Lastly, apply a thin layer of Mucopren® silicone sealant to the prepared area of soft liner. It is advisable to place a small amount of Mucopren® silicone sealant into a suitable vessel (e.g. the plastic one supplied in the pack) and then apply it with a brush within 90 seconds (see Fig. 3). The silicone loses its adhesive

properties after 6 minutes and 30 seconds. Please note: The silicone sealant does not attain its final mechanical properties until it has been at mouth temperature for several hours. When relining indirectly, apply adequate amounts of separating agent to the model (use a separator which forms a microfilm e.g. Dentsply Isolant®). As agar-agar based separating agents may form a culture medium for micro organisms such as Candida albicans, they must not be used. The reline jig or flask can be placed in a pressure vessel with water at a temperature of ≥ 50 °C/122 °F for at least 30 minutes to ensure a uniform setting time.

Storage conditions:

Store in a dry place at room temperature; do not expose to sunlight and avoid exposure to extreme temperature fluctuations.

Disinfection:

Soft lined dentures can be disinfected using, for example, Silosept®. (immersion disinfection)

Trademarks

Applyfix® 4, Mucopren® and Silosept® are registered trademarks of Kettenbach GmbH & Co. KG.

Note

Selected Kettenbach materials are available in certain markets only.

Limitation of liability
















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However, users must comply with and consider all recommendations and information in connection with any use.

Updated: 19th december 2011

Legend

Conformity with MDD 93/42/EEC		Use by	
ID number of the designated location	0123	Keep dry	
Keep away from sunlight		Catalog number	REF
Batch code		Caution, consult accompanying documents	
Dual system (Germany only)		Diameter	
Cartridge		Static mixing tip MB (single use)	
Adhesive			
Mixing tip Type B	MB	Single use	
Rx only For professional use only. Caution: Federal (U.S.A.) Law restricts this device to sale by or on the order of a dentist.		Temperature limitation	
Millimeter	mm	Milliliter	ml
Less than or equal to	≤	Greater than or equal to	≥
F Highly flammable		Xi Irritant	

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