

For better dentistry

DENTSPLY

Visco-gel

Temporary Soft Denture Liner

**Temporäres, weichbleibendes Prothesen-
Unterfütterungsmaterial**

Agent de rebasage temporaire

Materiale Provvisorio per Ribasatura Morbida

Rebase temporal para dentaduras

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Temporary Soft Denture Liner

Caution: For dental use only.

In the USA: Rx only

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1 Product description

Visco-gel is a temporary soft denture liner and tissue conditioner.

Visco-gel is a well-established brand that has been successfully used by dentists for more than 30 years.

Visco-gel complies with ISO 10139-1:2005 for resilient lining materials for removable dentures - part 1 - short term use.

Type B - allows extended time before removal from the mouth (more than 5 min.).

Visco-gel is an elastomer based on polyethylmethacrylates and plastisizers.

1.1 Composition

Visco-gel soft denture liner:

- **Powder:** Polyethyl methacrylate
- **Liquid:** Ethanol, Phthalyl butyl glycolate, Dibutyl phthalate

Visco-gel separator:

- Paraffin, Peppermint oil

1.2 Indications for use

Prior to denture replacement, extension or rebasing.

- Tissue conditioner where the denture-bearing tissues have become disturbed by either denture trauma or infection.
- Temporary lining immediately after extraction or oral surgery.

Temporary soft liner when normal dentures are not tolerated, particularly for patients with impairment of general health.

Function impression material in post-operative cases or when ill-fitting dentures require replacement or rebasing.

1.3 Contraindications

Do not use in patients with a known allergy to methacrylates or other components of the product.

2 General safety notes

2.1 Warnings

Visco-gel Liquid contains phthalyl butyl glycolate and as a side product dibutyl phthalate.

Unmixed Liquid:

- May be irritating to skin, eyes or respiratory system.
- May cause harm to the unborn child.
- May have possible risk of irreversible effects.

Mixed Visco-gel contains polymerized methacrylate.

- **Avoid eye contact** to prevent irritation and possible corneal damage. In case of contact with eyes, rinse immediately with plenty of water and seek medical attention.
- **Avoid skin contact** to prevent irritation and possible allergic response. In case of contact, reddish rashes may be seen on the skin. If contact with skin occurs, immediately remove material with cotton and wash thoroughly with water and soap. In case of skin sensitisation or rash, discontinue use and seek medical attention.
- **Avoid swallowing.** If accidental swallowing occurs let patient drink plenty of water. If nausea or illness develops, seek medical attention.

2.2 Precautions

- This product is intended to be used only as specifically outlined in the directions for use. Any use of this product inconsistent with the directions for use is at the discretion and sole responsibility of the dental practitioner.

The following precautions assure the safe handling of Visco-gel:

- **Avoid exposure:** Wear protective glasses, mask, clothing and gloves (nitrile, butyl or fluoride rubber gloves are recommended). Protective glasses are recommended for patients.
- Keep container tightly closed and in a well-ventilated place.
- Keep away from sources of ignition. Do not smoke.
- In case of an accident or if you feel unwell, seek medical advice immediately.

2.3 Storage conditions

All products should be used at room temperature. Inadequate storage conditions may shorten the shelf life and may lead to malfunction of the product.

- Store at temperatures between +10 °C and +24 °C.
- Keep the product out of sunlight.
- Do not use after expiration date.

2.4 Adverse reactions

Reversible inflammatory changes of the oral mucosa might occur in susceptible persons.

3 Step-by-step instructions

3.1 Isolation of Denture, Dosage and Mixing

Isolation

Apply a thin film of Visco-gel Separator to the non-fitting (occlusal and polished) surfaces of the dentures. Avoid getting any separator on the fitting (impression) surface of the denture as this will prevent adhesion.

Mixing

To obtain the correct powder/liquid ratio fill the appropriate measure to the indicated line, tapping lightly in the case of the powder.

The recommended ratio is:

1 measure powder (3 g) and 1 measure liquid (2.2 ml).

If a stiffer mix is required, slightly more powder can be used. An increase in the liquid is not recommended.

Dispense one measure of powder into the mixing vessel, add one measure of liquid (2.2 ml) and **mix for 30 seconds** (at room temperature).

3.2 Visco-gel as a Tissue Conditioner

Technique

1. Apply a thin film of Visco-gel Separator to the non-fitting (occlusal and polished) surfaces of the dentures.
2. Cover the entire fitting surface of the denture with Visco-gel. When the mixed material has reached a suitable consistency **insert into mouth**; this is normally **2-3 minutes from the start of mix** (at room temperature).

Because of the sticky nature of Visco-gel, it is recommended that areas of mucosa which may come into contact with the material should be moistened.

3. Instruct the patient to close the mouth gently into normal occlusion and to remain in this position for not less than two minutes.
4. The patient should then be instructed to carry out functional jaw movements, gently chewing and swallowing for instance, for at least two minutes.
5. At about 7-8 minutes from the start of mix, remove denture and check for adequate coverage, particularly at the borders. Additional material may be added, if required, by repeating the above procedure.
6. Remove any excess material with a sharp instrument or hot knife, take care to avoid disturbing the peripheral roll.

After a few days recall the patient and relieve any areas deficient in Visco-gel, applying further material to these relieved areas. If easing has been extensive a complete second application may be desirable.

Continue this treatment, periodically, until the tissues have returned to normal.

After completion of treatment the following courses of action may be followed:

1. Apply Visco-gel lining as a soft liner
2. Use final Visco-gel lining as a functional impression for new denture
3. Use Visco-gel lined denture as a special tray for final impression
4. Discard existing denture and take new impression in the orthodox manner prior to constructing a new denture.

3.3 Visco-gel as a Temporary Soft Liner

Preparation

After cleaning the denture grind down areas that require relief such as pressure points and undercuts. Rinse with water and dry thoroughly.

Apply a thin film of Visco-gel Separator to the non-fitting surfaces of the dentures. Avoid getting any Separator on the fitting surface of the denture as this will prevent adhesion.

Apply Visco-gel to the prepared denture as described in the section on tissue conditioner.

Note: The eventual loss of resilience or surface discolouration (app. 8 weeks) will indicate the necessity to remove the Visco-gel lining and to replace it with fresh material.

3.4 Visco-gel as a Functional Impression Material

When ill-fitting dentures require replacement (or re-basing) Visco-gel can be used as a functional impression material.

Apply Visco-gel to the existing denture, as described above, and allow to remain in the mouth for 24-48 hours.

When the patient is recalled after 2 days immediately cast a model from the Visco-gel functional impression.

Note: Delay in casting may result in reduced accuracy and fit of the new denture.

Process the denture to be rebased or the new denture on cast model in the normal manner. With care it is often possible to remove the denture from the model with the lining intact, in which case the denture may be returned to the patient to wear until the new denture is available.

3.5 Use as a Special Tray

During the final stages of tissue conditioning an ideal peripheral extension may be produced by the patient over some days of functional use. However it may still be considered desirable to obtain a final impression with even greater accuracy of detail. In such cases the lined denture may be used as a fitting special tray in which to place a final wash impression material.

3.6 Maintenance of Visco-gel treated Dentures

After 1 day in the mouth Visco-gel treated dentures can be cleaned by standard methods applied for the maintenance of removable methacrylate based dentures.

The eventual loss of resilience or surface discolouration (app. 8 weeks) will indicate the necessity to remove the Visco-gel lining and to replace it with fresh material.

3.7 Removal of Visco-gel from Dentures

Coat the entire surface of the Visco-gel with a thin film of separator and leave for 30 seconds. The material can then be removed using a laboratory tungsten carbide (TC) bur or trimmer or Moloplast cutter. In the absence of separator use a sharp instrument such as a 'half-round' sculptor.

4. Cleaning, disinfection and disposal

4.1 Cleaning of Containers, Measurers and Instruments

To prevent Visco-gel containers and measurers from exposure to spatter or spray of body fluids or contaminated hands it is recommended that the containers and measurers are handled offside the dental unit with clean/disinfected gloves.

Repeated disinfection of the containers may damage labels.

Spatulas, mixing slabs and instruments should be cleaned immediately after use with alcohol or acetone.

4.2 Disposal

If you spill Visco-gel, wipe the liquid with a cloth or paper towel. Cleaning towels with small quantities of Visco-gel could be disposed of as household garbage.

Waste material of Visco-gel must not be disposed together with household garbage. Do not allow product to reach sewage system. Visco-gel must be disposed of as hazardous waste in accordance with the official regulations.

5 Lot number () and expiration date ()

1. Do not use after expiration date. ISO standard is used: "YYYY/MM".
2. The following numbers should be quoted in all correspondence:
 - Reorder Number
 - Lot number
 - Expiration date

6 Contact

If you have any questions, please contact:

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