





### WHITEsmile® GmbH

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The treatment result must be determined and documented with photographs.

#### After tooth whitening

Apply fluoride gel/solution (colorless), e.g., After Whitening Mousse – reduces sensitivity and promotes remineralization.

Apply a thin layer of After Whitening Mousse to the teeth with a finger (wear gloves) and leave on for approx. 10–15 minutes. The patient can also leave the practice with After Whitening Mousse applied.

Tea, coffee, red wine, cigarettes and coloring foods should not be consumed for at least 4 hours after tooth whitening.

## Internal tooth whitening of endodontically treated, non-vital teeth.

The tooth is pretreated as described above. The whitening gel is also applied to the endodontically treated cavity. Do not activate the light within the cavity. It can be started no earlier than one week after the root canal treatment. Before use, ensure that the root canal system is completely sealed apically and at the bottom of the pulp chamber. Inadequate sealing can cause the active substance to diffuse into the surrounding tissue and result in side effects such as external root resorption.

- Remove the filling material from the cavity down to the depth determined using radiographic imaging. Also remove temporary materials
- 2. Seal root filling apically with approx. 1–2 mm glass ionomer cement. Remove the root canal filling up to the enamel-cement interface, preferably 1 mm above it.

- 3. Proceed according to the instructions for vital teeth. Apply Gingiva Protector. Apply whitening gel to the cavity, cover the tooth structure with 1–2 mm of gel.
- 4. In addition, apply whitening gel to the outer surface of the tooth. Leave on for 15–20 minutes, then suction off. Repeat the process 1–2 times. Do not activate the light in the cavity.
- 5. After the last application, suction off the whitening gel and rinse the cavity thoroughly.
- 6. Seal the cavity with an eugenol-free temporary restoration.
- 7. Final closure of the canal after approx. 2 weeks, see section Interactions.

#### Application notes

The whitening result may change by a few shades in the days following the treatment. The result of tooth whitening cannot be guaranteed, as tooth discoloration has different causes. Restorative materials such as composite fillings are not whitened. Lack of or inadequate gum protection can lead to irritation and sensitization. One mixing tip can be used for all cycles within a session. The product is intended for single patient use only and must not be reused. After treatment, existing white spots, e.g., in the case of fluorosis, may become more visible; this is usually a temporary effect. The duration of treatment depends on the sensitivity of the teeth, the desired degree of whitening and the type and extent of discoloration.

#### Warnir

Serious incidents in connection with this medical device must be reported to WHITEsmile GmbH and the competent authority.

The manufacturer is not liable for misuse. Please always observe the current safety data sheet.

#### Tooth whitening gel

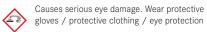
The colorless component of the double-chamber syringe is strongly acidic, the second component is strongly alkaline. When unmixed, both are highly corrosive. Always use the mixing tip supplied.

In case of contact with eyes: Rinse carefully with plenty of water for several minutes. Remove contact lenses if possible. Continue rinsing. Consult a doctor.

If swallowed: Rinse out mouth. DO NOT induce vomiting.

In case of contact with skin: Wash carefully with plenty of soap and water. Moisturize with a cream.





#### Gingiva Protector

In case of skin irritation or rash: Seek medical advice/attention. Allergy potential due to acrylates.



May cause allergic skin reactions. Harmful to aquatic organisms, with long lasting effects.

#### Storage and shelf life

Store fläsh Light Whitening Gel tightly closed at 4-12 °C.

Store packs as indicated. Protect from heat and sunlight and do not freeze. Keep out of the reach of children.

Do not use after the expiry date.

Improper storage may result in pressure build-up in the syringes and the components may leak out when opened.

#### **Disposal instructions**

fläsh Light Whitening Gel must be disposed of in accordance with the applicable requirements for hazardous waste. If the syringes have not been completely squeezed out, close them again with the sealing cap and dispose of them closed. Never squeeze out double-chamber syringes unmixed into the waste container for disposal. The resulting heat can ignite other waste components, e.g., paper, and cause a fire. Gingiva Protector must not be disposed of in wastewater.



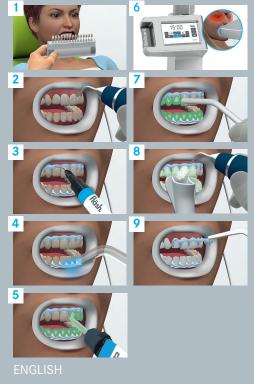
# Chairside Light Whitening System

Tooth whitening system Instructions for use for dentists Medical tooth whitening

REF 204 Version 6.3 10/2025







## Instructions for use for fläsh Light Whitening 32% HP (mixed)

fläsh Light Whitening is a 2-component gel for whitening pathologically discolored teeth for use in adult patients (≥ 18 years). It is only intended for professional, medical whitening in dental practices. The product is activated by automatically mixing the two components. The product complies with the EN ISO 28399 standard.

fläsh Light Whitening is a light-assisted gel and optimized for tooth whitening with the fläsh Whitening Lamp.

#### Intended purpose

fläsh Light Whitening is used for the fast, medically indicated whitening of pathologically and severely discolored, vital and non-vital teeth in cases where the natural or normal tooth shade cannot be restored by professional tooth cleaning.

The Gingiva Protector is a light-curing resin designed to protect the gums from chemical burns caused by high-concentration hydrogen peroxide during tooth whitening treatment. The After Whitening Mousse is used for remineralization and desensitization after tooth whitening or prophylaxis. The Lip Retractor keeps the lips away from contact with tooth whitening gels to protect the lips from chemical burns.

#### Indications

fläsh Light Whitening is used for the fast, medically indicated whitening of pathologically and severely discolored, vital and non-vital teeth in cases where the natural or normal tooth shade cannot be restored by professional tooth cleaning. Discolorations are considered medically indicated if they lead to a deterioration in

the patient's (oral health-related) quality of life as the tooth shade varies from the norm. If necessary, whitening can also be used as an alternative to covering the affected teeth with veneers or crowns.

Examples of the causes of such (intrinsic) discoloration are tetracycline/minocycline discoloration, moderate to severe dental fluorosis, non-vital teeth (pulp necrosis) – e.g., due to trauma, genetic or age-related (degenerative) discoloration, porphyria or icterus/jaundice and heavy deposits of food with penetration into the tooth substance by extrinsic pigments.

Tooth shades considered natural or normal are those that are commonly found in the population in terms of brightness, translucency and color. The Vita A1-D4 classical shade guide (for the most frequently occurring natural colors) and the separately available questionnaire (OHIP-G19) for determining oral health-related quality of life are used as aids for establishing a diagnosis and indication.

Application is carried out on single or several vital or non-vital teeth. It is also suitable for whitening individual, endodontically treated non-vital teeth, including intracoronal whitening.

#### Target patient group

The product is intended for adult patients (≥ 18 years) with pathological tooth discoloration. It is intended for single use and must not be reprocessed. The duration of treatment depends on the sensitivity of the teeth, the desired degree of whitening and the type and extent of discoloration.

#### Contraindications

Do not use in patients under 18 years of age, during pregnancy or breastfeeding and in anesthetized patients. Discoloration that can be removed during professional tooth whitening. Application is also excluded in the case of inflamed gingiva, exposed dentin / tooth necks, defective filling margins or untreated primary or secondary caries. Tooth whitening should be avoided in severely traumatized, non-vital teeth, as there is an increased risk of undetected crack formation and resulting cervical root resorption.

#### Side effects

Sensitivity or pain may occur during or after the treatment. This usually subsides quickly. In the event of severe sensitivity, shorten the exposure time or discontinue treatment and continue in several sessions if necessary. During endodontic whitening, inadequate root canal filling can lead to damage to the periodontium and even tooth loss. Organic amines contained in the product may cause allergic reactions. The gum protection can cause allergic reactions due to acrylic resins.

Hydrogen peroxide can inhibit radical polymerization and thus impair the adhesion of composite fillings or bracket bonding. Such treatments should be carried out no earlier than two weeks after tooth whitening.

#### Content

fläsh Light Whitening Gel: Aqua, Hydrogen Peroxide, Silica, Glycerol, organic amines, polyglycols, coloring agent.

Gingiva Protector: Oligomeric Urethane Acrylate, Medium Chain Triglycerides, Polyacrylic Acid, Difunctional Acrylates, Silica, Zinc Oxide, photoinitiators, pigments.

After Whitening Mousse: Aqua, Xylitol, Glycerin, Potassium Nitrate, Cetyl Alcohol, Tromethamine, Polyacrylic Acid, Titanium Dioxide, Di-Sodium Hydrogen Phosphate, Sodium Fluoride (1450 ppm F), Methylparaben, aroma.

#### Application

Tooth whitening should always be carried out before new visible restorations, as restorations cannot be whitened. Existing restorations may differ in shade after treatment. For single-tooth whitening, cover any teeth not being treated and prosthetic restorations (e.g., crowns) with moist gauze. During treatment, the patient should be placed in a slightly inclined position (approx. 45°) to facilitate swallowing.

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- Diagnosis by the dentist before starting treatment
- 2. Professional tooth cleaning 1-2 weeks before whitening.
- 3 Determine and document the initial tooth shade
- 4. Protect lips with lip balm, insert lip/cheek retractor patient should close their teeth on the lip retractor with light pressure, the patient should wear protective goggles.
- 5. Apply Gingiva Protector: Dry the gingiva with air, attach the application tip firmly, apply the material in quadrants 3–5 mm wide to the gums and approx. 1 mm to the neck of the tooth, carefully

seal the interdental spaces. Cure with a polymerization lamp in an arc-shaped movement for approx. 25 s (smaller areas ≥ 10 s). Avoid overheating from leaving the curing light in one place for too long.

- Check for leaks and seal open areas.
- 7. For single-tooth whitening, cover teeth that are not to be whitened and prosthetic restorations with moist gauze.

#### Tooth whitening

The product should be used at room temperature. The mixing tip is placed on the double syringe, a small amount of gel is squeezed out and only homogeneous light green gel is used. The patient and practitioner wear protective goggles.

- 1. The whitening gel should be applied in a layer of at least 1 mm on the labial surfaces of the teeth to be treated.
- The fläsh Whitening Lamp must be positioned and switched on in accordance with the instructions. The recommended application time is 15 minutes per cycle. In case of sensitivity, the pulse mode of the lamp can be activated or the power or treatment time reduced.
- 3. Suction off the whitening gel at the end of the cycle (do not rinse).
- 4. Further treatment cycles: Repeat steps 1 to 3. The maximum treatment time is 60 min (4 × 15 min), 45 min (3 × 15 min) is recommended. The duration depends on the discoloration, desired degree of whitening and sensitivity.
- 5. After the last cycle: Suction off the whitening gel and then rinse thoroughly with water. Remove the gum protection starting from the edge with a blunt instrument, remove the lip retractor and allow the patient to rinse with warm water.

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