



InnoWhite® Pro HP35 In-office Whitening System

Dental Whitening System for chair side use in the dental clinics for discoloured vital and non-vital teeth, only to be used by dental professionals.

Keep refrigerated 4°C - 12°C. Do not freeze.

WARNING: Keep out of the reach of a child.

According to the Medical Device Directive 93/42/EEC.

InnoWhite Pro HP35 complies with Standard EN ISO 28399.

The expiry date on the package or syringe refers only to products that have been stored correctly.

Do not freeze the gel and protect it from heat and sunlight.

IMPORTANT NOTE: Please carefully read and understand the instructions before proceeding with the tooth whitening treatment.

Descriptions

Pro HP35 is a two-component material for whitening discoloured teeth and contains 35 % hydrogen peroxide upon mixing. It is intended only for professional whitening in the dental office. The bleaching agent is activated upon mixing of the two-component material. The duration of treatment is determined individually and depends on the teeth and soft tissue conditions, the desired degree of whitening and the nature and extent of tooth discoloration. The recommended treatment duration is 15 minutes per cycle for 3 cycles with using LED light of wavelength of between 450-490 nm. For treatment without the use of light (chemically-activated), 20 minutes per cycle is recommended. The Pro HP35 in-office kit is formulated for use with InnoWhite EA/IW-05 LED whitening lamp to achieve the best result.

The coloured gel can be applied directly from the mixing tip to the teeth – the gel's consistent viscosity will prevent dripping or over flow. Unused gel can be kept until the end of the shelf life in the closed syringe. It can be used, along with a new mixing tip, for another treatment.

Indication for use

InnoWhite Pro HP35 is used for fast, medically indicated whitening of strongly discoloured, vital and non-vital teeth, which cannot be converted back by a professional dental cleaning into the natural or normal tooth colour. Medically tooth whitening is indicated when discolorations lead to a deterioration of quality of life of the patient due to their abnormal deviating tooth colour. Medical tooth whitening can also be used as an alternative to (significantly more invasive) conservative treatment of the affected teeth with veneers or crowns.

Tooth colours, as they normally appear in their brightness, translucency and colour in the population, are considered natural or normal. For diagnosis and indication e.g. the A1-D4 Vita classical shade guide can be used (for the most frequently occurring tooth colours). Examples of the causes of such (intrinsic) discoloration are: moderate to severe dental tetracycline/minocycline discolorations, moderate to severe dental fluorosis (TF index= 2), non-vital teeth (pulp necrosis) e.g. by trauma, genetic or age-related (degenerative) discoloration, porphyria, or jaundice, heavy deposits of foods with penetration into the tooth substance (intrinsic discoloration by extrinsic dyes). It can be used to whiten single or multiple teeth or parts of teeth. It can also be used for whitening of single endodontically treated non-vital teeth including intra-coronal bleaching.

Application

Prior to treatment

Before the whitening treatment a diagnostic indication for "medical indicated tooth whitening" must be defined by the dentist. After examining the patient, the current tooth color shall be documented. Professional tooth cleaning is indicated prior to the whitening treatment. Since restorative materials will not be whiten, it is recommended the teeth whitening treatment should be performed prior to placing aesthetic restorations. Any dental work such as crowns, fillings etc. should be done 1-2 weeks after the treatment in order to match the color of the newly whitened teeth.

1) The teeth should be kept free by using a lip retractor or similar instrument. If necessary, use cotton rolls and apply a lip care such as Vaseline to the patient's lips.

2.) Application of the **InnoDam** – Gingival Protector is an easy to apply light-curing resin, which allows optimal covering of soft tissue and neighboring teeth during whitening. It is also suitable to cover exposed tooth necks and filling materials during the treatment. Attach the dispensing tip to the syringe. Dry the gingival carefully to ensure that the Gingival Protector will hold and seal during the whole treatment. Apply the Gingival Protector directly on the gingival and cover 3-4 mm of the gingival and 0.5-1 mm of the teeth.

Light cure the gingival protector in an arching movement for about 25 seconds. Alternatively, use the EA/IW-05 LED whitening lamp to cure the entire upper and lower arch for 3-4 minutes. When finished, use dental mirror to check if the seal is tight and no pinkish gingival is visible. Close open spots again with Gingival Protector and light cure. Instead of the Gingival Protector, a rubber dam can also be used for the isolation.

3.) **Whitening procedure** - The gel should be used at room temperature. Attach the mixing tip to the top of the dual-barrel Pro HP35 syringe. Verify the flow of the gel on gauze or mixing pad, prior to the intra-oral application. Apply the gel directly to the surface of the teeth. The gel should be applied about 1-2 mm thick (avoid contact with other parts of the body and clothes). The patient should be positioned in a slightly declined position (45° degree angle) during the whitening process to allow swallowing of the saliva comfortably.

Allow the gel to work for about 15-20 minutes. Reduce the application time and cycles if the patient experiences sensitivity.

Remove the gel from the teeth using suction and do not rinse. Apply a fresh layer of gel onto the teeth. Repeat this process for three cycles. Maximum treatment time is 60 minutes - 3x 15-20min. After the last cycle, remove the gel first using suction and then rinse it off with water.

Remove the Gingival Protector and lip retractor.

Finally, the patient should rinse their mouth with warm water.

The tooth color after the treatment should be documented for shade comparison.

Apply **InnoSense** desensitizer to the teeth and gum areas and leave it on for about 10 minutes to alleviate the sensitivity, if any. The remaining of the InnoSense should allow the patient to bring back home and apply when necessary.

Internal bleaching of endodontically treated, non-vital teeth

Wait at least one week following the endodontic procedure before performing an internal tooth whitening and ensure that the tooth is endodontically sound.

1. Check the X-rays, to ensure that an adequate apical endodontic sealer is in place and to check where the alveolar bone margin runs.

2. Remove the filling material from the access hole until the depth is defined based on the X-ray image. Continue to remove the filling material and/or temporary endodontic materials in order to allow the tooth whitening agent to get in contact with the internal structure of the tooth for best result.

3. Seal the root with conventional glass ionomer cement. Apply a 1-2 mm thick layer to ensure a secure seal.

4. The internal whitening is performed according to the instructions for vital teeth. Cover the gingival around the tooth with Gingival Protector. Apply InnoWhite Pro HP35 gel into the cavity and make sure the tooth structure is covered with 1-2mm gel. Apply the gel also on the outside surface of the tooth. Wait for 15-20 minutes follow by suction of the gel. Repeated the procedure for 1-2 times. After the last application, remove gel by suction and rinse off remaining gel from cavity.

5. Use non-eugenol temporary restorative material to seal the opening.

6. Before starting to work on adjacent teeth, it is recommended to wait for at least two weeks after the whitening treatment - in order to stabilize the tooth color.

Side effects

Sensitivity and irritation of the teeth with more or less pronounced pain during or after treatment can occur in some individual cases. This effect is temporary and typically will disappear within a short period of time of not more than 24 hours. In case of excess sensitivity of the teeth during treatment, the exposure time of the bleaching agent must be shortened or discontinue the treatment. Nonetheless, to obtain an acceptable bleaching result, whitening should be conducted over several sessions in such cases.

Sometimes after the whitening treatments white spots may appear on the teeth surfaces. These spots are mostly from fluorosis that has not been visible before. After a period within a few days these white spots will disappear upon rehydration.

Some studies refer to a temporary change in the organic dental matrix as well as a reduction in the microhardness of enamel and dentine, however without any pathological relevance. In the case of endodontic bleaching, an inadequately performed root canal filling which does not reach or exceed the enamel cement border, may lead to damage of the periodontium (external root resorption) or even loss of the tooth.

It is essential for gingival protection to be extended over the tooth neck (approx. 1 mm). Inadequately applied gingival protection can lead to irritation of the gingival through contact with peroxide. In this case the bleaching therapy must be discontinued, and the tooth must prepared anew after thorough rinsing and drying.

Contains small amounts of organic amines. These can cause allergic reactions when in contact with skin or mucosa.

Sensitivity of the teeth can be reduced with a subsequent application of InnoSense.

Contraindications

InnoWhite Pro HP35 gel should not be used in the following cases: stains which can be removed by suitable polishing agents and rotating brush during a professional tooth cleaning, pregnant and lactating woman due to lack of studies, known allergy to any of the ingredients, exposed dentin, faulty edges of fillings, untreated primary and secondary caries, very heavy smokers and alcoholics, persons under the age of 16, and under general anesthesia.

Interactions

Hydrogen peroxide weakens the polymerization of polymers. Therefore, composite fillings or bracket bonds should not be performed any time within 2 weeks after a whitening treatment, due to the lack of adhesion.

Special notes

For at least 24 hours after whitening treatment, the patient should avoid consuming colored drinks such as tea, coffee, red wine, cigarettes etc. as this will reduce effectiveness of the whitening treatment. The bleaching effect can intensify for a few days after completing treatment. The result of bleaching treatment cannot be guaranteed as tooth discoloration may be due to a variety of causes. The bleaching effect can change in few shades in a period of a week after completing the treatment.

Any existing amalgam and/or composite fillings are not bleached. The restorations are best to be renewed two weeks after whitening bleaching treatment.

Orthodontic work (bonding brackets) should either be performed prior to bleaching therapy or no earlier than 2 weeks after (impaired adhesion to teeth).

Warnings

Because of the high concentration of Hydrogen Peroxide InnoWhite Pro HP35 gel is highly reactive. To avoid contact with skin or eyes we recommend the use of gloves and safety goggles. If stored improperly, the syringes may become pressurized and lead to uncontrolled spillage of gel when opening.

For safety reasons, the patient should also wear safety goggles. If the gel does come into contact with skin, remove it and rinse immediately with water. White spots may appear in the affected area and the patient may experience some burning sensations. The symptoms should disappear after approx. 30-60 minutes. If the gel comes into contact with the eyes, rinse immediately with water and consult a doctor.

Notes on disposal

Full syringes must be sent for special disposal in accordance with regulations on special waste. This product was developed for use in dentistry and must be used in accordance with the instructions for use. The manufacturer cannot be made liable for any alternative use. In addition, the user is obliged to check the material at his own responsibility for its suitability and application for the intended purposes, especially if these are not listed in the instructions for use.

Symbols

Batch description

Expiry date

Observe instructions for use

Recommended storage temperature

Manufacturer

Harmful if swallowed

Ingredients

Aqua, Hydrogen Peroxide, Silica, Glycerol, Organic Amines, Potassium Nitrate, Sodium Fluoride, Polyglycols and Coloring Agent

InnoWhite®
Professional Dental Whitening System

Made in Europe

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