

INSTRUCTIONS MANUAL

whiteness^{HP} **BLUE**
CALCIUM

**IN-OFFICE TOOTH BLEACHING SYSTEM
FOR PROFESSIONAL USE ONLY**



Read carefully all the information in this product information sheet before using the product. Keep it for reference until total consumption of the product.

Product Description:

Whiteness HP Blue is a product that gathers the technology of the best bleaching dental systems and the new worldwide dentistry tendencies towards conservative and safety techniques for in-office bleaching procedures. Whiteness HP Blue is a 20 or 35% hydrogen peroxide gel. Its formulation is based on the precursor Whiteness HP Maxx bleaching system; however changes in the mode of application and in the composition were introduced in order to increase the efficacy of the new material even under low hydrogen peroxide concentration. Besides the basic formulation of the Whiteness HP Maxx, calcium was also added to the Whiteness HP Blue with the aim to minimize enamel demineralization. A new activator system was included to maximize the performance of the product and eventually a new blue pigment that does not change color throughout the bleaching procedure was also added in order to facilitate the visual control during product application. Regarding the mode of application, the product does not require any light activation (light curing devices, laser, plasma arc unit, etc.) and the bleaching gel is applied just once in each clinical appointment (40minutes for 35% and 50 minutes for the 20% Whiteness HP Blue. The product presentation is also new. The amount of gel that is prepared is enough for bleaching both dental arches and its application is done by means of a syringe. To maintain chemical stability and due to the catalytic potential, the product still keeps the thickener and hydrogen peroxide phases separated, being them mixed only prior to the bleaching procedure. As a safety of measure to the customer, a neutralizing solution is also included in the kit to neutralize the hydrogen peroxide in case of accidental contact with soft tissues. This solution is based on 1.25% catalase enzyme stabilized in a harmless special solvent, capable to decompose hydrogen peroxide in a very fast rate thereby neutralizing its deleterious effect to the soft tissue. However, the action of the neutralizing solution is restricted to the neutralization of the hydrogen peroxide, being the solution incapable to reverse the soft tissue injuries caused by the hydrogen peroxide.

The product is indicated in the following cases:

Physiological darkening of vital teeth due to age. Very chromatic vital teeth (yellow or darker appearance). Vital discolored teeth due to incorporation of pigments from some substances such as coffee, tobacco, tea, etc. More challenging cases (severe darkening cases): this product can be associated with at-home vital bleaching. The 20% Whiteness HP Blue is more indicated for bleaching young teeth and those cases considered less challenging. This concentration also follows the tendency towards the search for a safer in-office bleaching procedure. This system presents a lower frequency of tooth sensitivity as it is based on a less concentrated hydrogen peroxide gel. Thus, 20% Whiteness HP Blue should be the first choice for patients with sensitive teeth. The 35% HP Blue version is indicated in more challenging cases such as very chromatic and mineralized teeth usually found in elderly people.

Note: It is important to observe that the literature points out that in-office bleaching procedure might lighten less and the resulting color stability is lower than the at-home vital bleaching, because in the latter the contact time between the bleaching gel and the dental structure is higher and more frequent than the former. The combined technique (at-home and in-office vital tooth bleaching) offers satisfactory results in resistant cases. For these reasons it is of paramount importance a perfect interaction between the professional and the patient. The dentist should instruct the patient about the likely results based on clinical evidence and on a shade guide. The professional should also inform the patient that the degree of whitening is also dependent on the patient's teeth saturation degree. In some cases, the patients will have their teeth bleached but not the level of their expectations. In-office vital bleaching employs a higher concentration of hydrogen peroxide and therefore might trigger higher tooth sensitivity during and/or after the bleaching procedure compared to at-home vital bleaching.

Product Indications:

Similarly to its precursor, Whiteness HP Blue is a product developed exclusively for in-office use and should be used only by qualified professionals, under dentist's supervision. The soft tissues should always be adequately isolated.

Presentation forms:

Whiteness HP Blue - Kit (6 applications):

06 syringe sets (1.2 g in each syringe set, 7.2 g of bleaching gel in total);
01 bottle of Neutralize solution with 2 g;
01 syringe of Top Dam with 2g and 6 tips (license number ANVISA 80172310023);
06 syringe attachment applicances;
06 application tips;
Instructions for Use.

Whiteness HP Blue – Mini Kit (2 applications):

02 syringes sets (1.2 g in each syringe set, 2.4 g of bleaching gel in total);
01 bottle of Neutralize solution with 2g;
02 syringe attachment appliances;
02 application tips;
Instructions for Use.

Whiteness HP Blue – Unit (1 application):

01 syringe set (1.2 g in each syringe set);
01 syringe attachment appliances;
01 application tip;
Instructions for Use.

Basic Composition:

Active ingredients: 20% or 35% hydrogen peroxide (after mixture of phases).

Inactive ingredients:

Thickeners, inert blue pigment (20% HP Blue) or inert violet pigment (35% HP Blue), neutralizing agent, calcium gluconate, Glycol and deionized water.

Precautions and Contraindications:

- The product should be indicated and used only under supervision and control of a dentist.
- The oral health conditions should be evaluated previously to the beginning of the bleaching treatment. Enamel fissures, microleakage in existed restorations, exposed dentin and other factors that might jeopardize the bleaching should be treated beforehand. The product is contra-indicated for patients that are not in good general and oral health conditions.
- Enamel cracks are very common and do not prevent the patient from having their teeth bleached, although acute tooth sensitivity might occur due to the fast penetration rate of the hydrogen peroxide to the dental structure. Generally, this acute effect is observed in some isolated teeth. Clinicians should be aware that patients might present some undetectable enamel fissures in which the diagnosis of their depth is even more difficult. Severe tooth hypersensitivity can be treated with a desensitizer agent (2% Desensibilize KF – FGM) during 10 minutes. If this treatment approach is not effective, the in-office vital bleaching time can be reduced and complemented by at-home vital bleaching.
- The product is not indicated for bleaching teeth with amelogenesis and dentinogenesis imperfecta, severe fluorosis, intense tetracycline staining and other enamel and dentin abnormalities that may affect tooth vitality.
- The product is not indicated to be used in teeth under anesthesia. The assessment of the tooth sensitivity during the bleaching procedure is essential. In cases where there is a non diagnosed tooth imperfection or dental structure crack, the hydrogen peroxide might penetrate in the pulpal tissue in a faster rate leading to pulpal necrosis.
- The use during pregnancy or lactation is not recommended as well as in patients under 15 years old.
- The product is not recommended for patients who have recently undergone gingival surgery, patients with gingival tissue inflammation or some allergic reaction to any of the components of the product.
- As it is a chemically activated system there is no need to employ light sources to accelerate the bleaching (LED systems, high power lasers and others).
- Enamel acid etching before bleaching does not potentiate the bleaching process and it is therefore neither required nor recommended.
- While handling the product, the professional as well as the assistant should wear protective gloves and eyewear. The patient should also use protective eyewear and other necessary protection to avoid accidental contact of the product with the skin and clothes.
- Whiteness HP Blue is a strong oxidizing agent able to cause white staining and temporary irritation when contacting live soft tissue. Fortunately, this usually disappears at most after 2 hours without any sequel.
- In case of accidental contact with skin or live soft tissues, neutralize the hydrogen peroxide with some drops of Neutralize solution and rinse throughout the area afterwards.
- This bleaching system is composed by the hydrogen peroxide (phase 1) and thickener (phase 2) that requires mixing before use. Care should be taken when handling phase 1 as it contains 30% and 50% hydrogen peroxide in the 20% HP Blue and 35% HP Blue, respectively.
- The content of the hydrogen peroxide syringe might be under pressure and might leak due to inadequate storage conditions. Before opening up the syringe, protect your skin and eyes (dentist and assistant) and check if there is drained liquid. In positive case, request the material replacement. Handle the product far away from the patient, in a sink or any other safe place, to avoid contamination of other people.

- Wash the hands and contaminated materials after using the product. Prevent accidents with safety measures when handling the product.
- Isolate gingival tissue from teeth to be bleached using the light-cured gingival barrier Top Dam or a conventional rubber dam associated with a lip retractor. Regardless the isolation technique it is of paramount importance to ensure an adequate seal and protection of the soft tissues.
- It is recommended to avoid the ingestion of acid drinks or food during bleaching as they might increase the teeth sensitivity triggered by the bleaching procedure. Chromatic drinks and foods should be avoided to not jeopardize the bleaching process for at least 24 hours after the bleaching procedure.
- Inform patients about success and failures possibilities of the bleaching procedure. Avoid frustrating patients' expectations.
- After mixing both phases, attach the application tip and check if the bleaching gel flows out easily before using it intra-orally. If resistance is felt, attach a new application tip and check material flow on an inert surface (i.e. mixing pad) to ensure evenness of flow.
- The product should be used according to the manufacturer's directions. Under no circumstance must the product be injected.

Precautions for Europe:

- Not to be used on patients under 18 years of age;
- The entire treatment must be performed only by the dentist;
- It is an alternative, conservative method for treating teeth discoloration caused by questionable to mild fluorosis staining and low severity of tetracycline/minocycline staining.
- Note the expiration date printed on the outer package/syringe.

Side effects:

- Some patients might experience tooth sensitivity during and after the product application. If the patient experiences tooth sensitivity, employ 2% Desensibilize KF. If tooth sensitivity still persists and treatment is discontinued, a new clinical appointment should be scheduled at minimum after 7 days. Check if there is any teeth abnormality that can be treated to minimize such tooth sensitivity. There are some cases where tooth sensitivity appears only after the bleaching protocol (one or two hours after). In case the patient experiences severe tooth sensitivity, an analgesic or a mild anti-inflammatory medicine can be prescribed, depending on the needs of each specific case. Areas of hypocalcification (hypoplasia), clinically not visible, occasionally exist. Because of mineralization differences, these areas will whiten faster than normal enamel and will become more visible during bleaching. In some cases, the remaining teeth can closely blend with hypocalcified areas after re-hydration. Treating these areas with fluoride application can also aid in their disappearance.

Instructions for use:

Read carefully the Warnings, Precautions, Contra-Indications and Possible Side Effects written in this Product information sheet, before the beginning of the treatment.

Getting ready for the bleaching treatment:

1. The dentist and the assistant must wear protective gloves, eyewear, mask, cap and clothing before handling the product. Protect the patient with cap, eyewear and adequate lip retractor (Arcflex – FGM) to avoid inadvertent contact of the gel with the patient's soft tissue.
2. Remove the bleaching gel from the package following safety measures Instructions.
3. Remove the cap from the thickener syringe and connect it in the syringe attachment appliance.
4. Attach the hydrogen peroxide syringe in the other side of the attachment appliance. Care should be taken as the hydrogen peroxide syringe might be under pressure.
5. Keep the set ready for mixture soon before application. Attention! Mix the contents of both syringes only after the preparation of the patient (in the moment of the bleaching gel use). The hydrogen peroxide syringes are exclusive for each version of Whiteness HP Blue and cannot be exchanged. The hydrogen peroxide syringe delivered in the 35% HP Blue is exclusive for this version and does not meet the requirements of the 20% HP Blue and vice-versa.

Vital Tooth Bleaching:

Examine the patient's oral cavity regarding the presence of dental caries, failed restorations, enamel fissures, recession in cervical areas, gingivitis, periodontal disease and/or other related problems that might be important to be treated before the beginning of the bleaching procedure. Provide your and the patient's protection.

STEP BY STEP vital teeth:

Employ the enclosed sequence of illustrations to follow the procedure description.

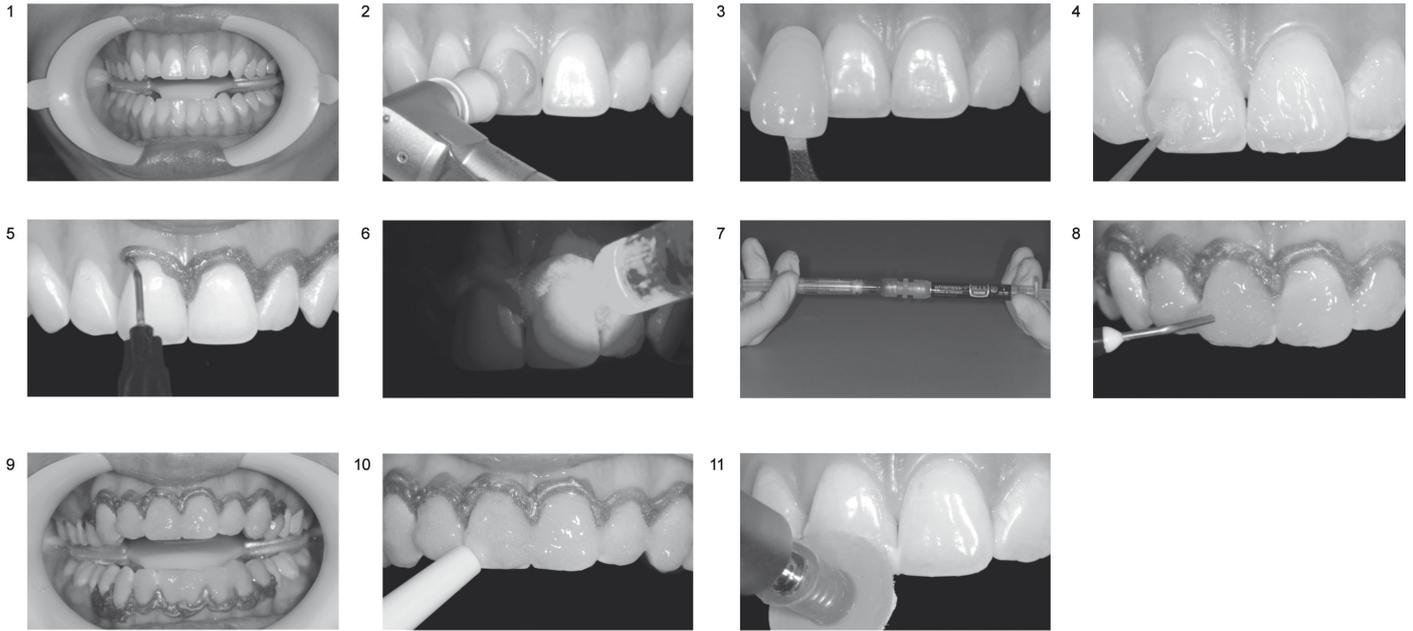


Figure 1: Place the lip retractor Arc Flex (FGM) to provide tongue and cheeks retraction.

Figure 2: Perform tooth prophylaxis with pumice and water.

Figure 3: Determine and record the shade with a shade guide before bleaching and take a picture to record the initial appearance of the case.

Figure 4: Apply the 2% Desensibilize KF for 10 minutes to provide a previous desensitization. The excess gel should be removed with an aspirating tip followed by rinsing and drying.

Figure 5: Perform relative isolation with the light-cured gingival barrier Top Dam in order to cover the marginal gingival tissue and the embrasures. The extension of the gingival barrier in the cervical to gingival direction should be 3 to 5 mm in a 1-mm thick increment. The gingival barrier should also cover 0.5 to 1 mm of the dental surface. A clinical mirror can help clinical to visualize the cervical area of the teeth (incisal to cervical view) in order to check if there is uncovered gingival tissue. In positive case, amend it. This step is crucial to avoid the contact of hydrogen peroxide with the gingival tissue. Employ a lip retractor to facilitate the gingival barrier and bleaching gel application.

Figure 6: Light cure the Top Dam during 20-30 s for each group of 3 teeth. The gingival barrier after light curing is rigid and insoluble preventing any injury caused by irritant products.

Figure 7: Bleaching gel preparation: Ensure both syringes are securely attached together before proceeding. Mix the contents of both phases by pressing the plungers of the syringes alternatively in opposite directions up to 8 times. Press entire mixed content to one of the syringes. The bleaching gel is then ready for use.

- Notes:**
1. Ensure that both syringes are securely attached to one another.
 2. Mix the phases in a separated place, out of the patient's reach.

Figure 8: Twist an application tip in the syringe with the bleaching gel and apply Whiteness HP Blue 0.5–1mm layer on the buccal surface (including the interproximal areas) of teeth undergoing bleaching. Extend slightly onto incisal/occlusal edges. Consider only the smile line (generally from right to left 2nd premolar).

Note: A 1.2g bleaching gel syringe set, is enough for simultaneous application in both dental arches.

Figure 9: Application typically last 40 minutes for 35% HP Blue and 50 minutes for 20% HP Blue, and a single application is done in each clinical appointment for both versions. Stir the bleaching gel onto the enamel surface every 5-10 minutes to release some oxygen bubbles that is released from the chemical reaction in order to maximize the contact of the gel with the dental surface.

Note: These application times are manufacturer’s suggestions and should be followed by the professional. Customized treatments, with shorter bleaching gel exposure times and even treatment interruption can be used in cases of tooth hypersensitivity.

Figure 10: Remove Whiteness HP Blue from teeth using an endodontic or surgical aspirating tip. After all visible gel is removed; follow with thorough rinse with abundant water. Lift gingival barrier from surface using an explorer.

Figure 11: Polish the buccal surface of teeth with Diamond Excel polishing paste and disc felts (Diamond or Diamond Flex – FGM)

Notes:

1. Monitor patient’s tooth sensitivity during procedure and check the likely areas of irritation due to contact with hydrogen peroxide. In case this is observed, discontinue the procedure and treat the occurrence (see comments on the Precautions and Side Effects sections).
2. In case the patient develops a non-controlled tooth hypersensitivity it is highly recommended the interruption of the treatment. Check if there is any teeth abnormality that might be blamed for such hypersensitivity, such as presence of fissures, dentin exposure, etc. If a new clinical appointment for in-office bleaching is not possible or recommended due to the aforementioned or any other reasons, the bleaching can be complemented with at-home vital bleaching agents (10% Whiteness Perfect 10%, for instance).
3. If after two clinical bleaching appointments the level of whitening has not met the patient’s expectations (severe darkening) and no significant tooth sensitivity is observed, schedule patient to repeat the product application up to two more clinical sessions, at least 7 days following the treatment. In the more challenging cases, the association of techniques (in-office and at-home vital bleaching) can be employed according to professional instructions.
4. Satisfactory results may be reached after just one clinical appointment. However it is recommended to repeat the product in another clinical session to improve the treatment effectiveness (2 sessions per patient).
5. Similarly to the other bleaching techniques, it is highly recommend to record the shade before the treatment beginning, to instruct the patient regarding the case perspectives (limitations in case of tetracycline staining, teeth with grayish shades, etc.), to inform the patient about the likely tooth sensitivity and the need of restoration replacement. Some teeth may not meet desired expectations because of unforeseen factors, peculiar enamel features or type of staining.
6. After syringe-to-syringe mixture, the bleaching gel should be consumed in the same clinical session. The bleaching gel cannot be stored to be used in another clinical appointment otherwise it will lack efficiency. In case some bleaching gel is not used this should be discarded. The product may be diluted in water and then thrown away in the sink.

Additional information:

Conservation and Storage:
For professional use only. It should be used only by qualified professionals. Do not use the product after the expiration date. Discard the product following the legislation of your country. Store the product at temperature between 5° to 30°C, 41° to 86°F. Do not freeze the product. Keep out of direct sunlight.

Warnings:
Do not use the product after the expiration date. Discard the product following the legislation of your country. Do not reuse the empty packing. Keep the product out of children’s reach.

Manufactured by:
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Responsible chemist: Friedrich Georg Mittelstadt
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Irritant.

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