

Technical Profile

Rev. 01 - Sep/09



In Office Vital Tooth
Bleaching System

whiteningHP **BLUE**
CALCIUM

You're Worth It. **FGM**

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1. Presentation

Whiteness HP Blue is a 20 or 35% hydrogen peroxide bleaching gel for in-office use only. 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 make it more effective 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 avoid mineral losses. Therefore, the new bleaching system lessens the enamel microhardness reduction that occurs due to the bleaching protocol, contributing to maintain the dental structure integrity. A new catalyst system was included in the formula to maximize the performance of the product. Also, new pigments were included (blue or purple according to the concentration) in order to facilitate the visual control during product application, as they do not change its color.

Regarding the mode of application, the product is very practical since Whiteness HP Blue does not require any external light activation (light curing devices, laser, plasma arc unit, etc.) and the bleaching gel is applied just once in each clinical appointment.

To maintain chemical stability and the catalytic potential, the product still keeps the thickener separated from the hydrogen peroxide phase. However, the bleaching system relies on a new presentation mode: two syringes (one containing the thickener and the other containing the hydrogen peroxide) are connected by means of a syringe attachment appliance and then both phases are homogenized easily. The application of the gel is performed with one of the syringes, after twisting the syringe tip in one of the syringes.

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 (lips, cheek, gingival tissue, tongue, palate, etc.). This atoxic 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, preventing further injuries to the soft tissues.

2. 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.

3. Modes of Product Presentation

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 appliances
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 syringe of Top Dam with 1 gram and two syringe tips (Reg. ANVISA 80172310023)
02 application tips.

02 syringe attachment appliances
Instructions for Use

4. Indications

Whiteness HP Blue should be exclusively used in-office, by qualified professionals. The soft tissues should always be adequately isolated.

The product is indicated in the following cases:

- Naturally darkened vital teeth (yellow or darker appearance)
- Physiological darkening of vital teeth due to age
- Vital discolored teeth due to incorporation of pigments from some substances such as coffee, tobacco, tea, etc.
- In case the patient submitted to the bleaching present a non-vital tooth, Whiteness HP Blue can be used externally or internally, during the in-office bleaching session. Additionally, internal bleaching gels such as Whiteness Super Endo or Whiteness Perborato can be applied inside the pulp chamber (walking bleach technique) by judicious clinical evaluation.

5. Main Characteristics

Self-catalyzed system: The exclusive formulation of Whiteness HP Blue contains catalysts that make the product more active and efficient, sparing the use of external activation sources.

Efficacy: The new catalytic composition allows the achievement of similar bleaching effectiveness regardless the concentration of the gel chosen (35% or 20%). Only different application times are recommended for each system, being 40 and 50 minutes respectively for each concentration.

Single application: The earlier bleaching system generations do not possess the technology of stable catalysts, therefore there is a need to refresh the bleaching gel every 15 minutes in order to renew its activity. The new self-catalyzed formulation eliminated this need. With Whiteness HP Blue a single application for a longer period of time is performed in each clinical appointment. This new application protocol turned the bleaching procedure more productive, simpler and faster.

Pre-dosed syringes: The proportion between the thickener and hydrogen peroxide phases is predetermined, which facilitates the preparation of the bleaching gel and contributes to the agility of the bleaching treatment. The total amount of product dosed in the syringe is enough to cover all the teeth of the line of the smile (from 2nd left premolar to 2nd right premolar) of both arches, without any wastes.

Easy homogenization of the phases: A pluggable syringe system allows easy mixture of the phases and guarantees perfect homogenization.

Easy application: The bleaching gel obtained after mixture of the phases possesses excellent consistency, homogenous color being highly visible and can be applied with one of the syringes, after twisting the syringe tip in one of syringes. The application with the own syringe facilitates the process and turn it faster.

Excellent wetting: Good wetting is an essential requirement for a bleaching gel as this feature facilitates the transfer of hydrogen peroxide to the dental structure. If a good wetting is not achieved (due to inadequate viscosity or incompatibility with the substrate) the hydrogen peroxide transfer is hampered, jeopardizing the final bleaching result.

Addition of calcium: Aiming to contribute with the maintenance of the dental enamel integrity, a source of soluble calcium was added to the bleaching gel formulation. Studies demonstrate that the presence of calcium in the bleaching gel contributes significantly for the reduction of the enamel microhardness drop that occurs after the bleaching protocol (Cavalli, 2007).

Safety: Following the tendency for the search of improved safety in the dental bleaching procedure without loss of effectiveness, the Whiteness HP blue was developed in a version containing 20% of hydrogen peroxide. Comparative studies among bleaching gels demonstrated that the tooth sensitivity frequency after the use of 20% HP Blue was lower than what was observed with the 35% version. Besides that, both concentrations spare the application of external activation light sources without jeopardizing the treatment.

6. General information

6.1 Mechanism of Action

As all bleaching products based on hydrogen or carbamide peroxide, the Whiteness HP Blue bleaching system acts through the penetration of the hydrogen peroxide in the dental structure and consequent oxidation of the pigments presented in enamel/dentin tissues. For didactic purposes, a sequential analysis of the main processes that occur during the bleaching procedure is described below:

6.1.1 Penetration of hydrogen peroxide in the dental structure

It depends strongly on the permeability of the enamel and consequently on available time for the process. The ability of the gel to interact with the enamel surface (wetting), the osmotic pressure that the gel generates to force the hydrogen peroxide to penetrate in the dental structure and the structural characteristics of the enamel are the factors that dictate the speed of this stage. The wetting of the substrate determines the quality of the interaction between the bleaching gel and enamel and consequently the easiness of hydrogen peroxide transfer to the dental structure. For this requirement, the solvent type or surfactant agent and the type of thickener has a critical role. Usually thickeners based on silica (pyrogenic silica, powder) and carbopol (polymer of high molecular weight) are not good options because they end up "binding" the hydrogen peroxide molecules. The hydrogen peroxide concentration, the solvent composition and the rheology of the system determine the osmotic pressure.

6.1.2 Reaction of hydrogen peroxide with the pigments

In order to promote the chemical reaction between the hydrogen peroxide and the pigments, some conditions are essential and the main ones are:

- The hydrogen peroxide needs to achieve the pigment site. The type of discoloration and the degree of difficulty to reach this site determine the amount of time necessary to accomplish this stage effectively.
- The hydrogen peroxide needs to reach the pigment site active and in an appropriate concentration so that there is an oxidation reaction and consequent breakdown of the chromophore (chemical interaction that determines the color to a substance). Due to its reactivity, the hydrogen peroxide can react or can be decomposed by a series of endogenous organic substances presented in the dental structure, which are not the ones responsible for the undesirable teeth shade. These reactions are known as competitive reactions as they consume hydrogen peroxide before the hydrogen peroxide reaches the pigment site. To avoid this undesirable hydrogen peroxide consumption and to allow its arrival on the pigment site in an active mode, two factors should be taken into consideration: the period of time the gel is maintained on the dental structure and the concentration of the product.
- The hydrogen peroxide needs to be in an appropriate condition to react when it reaches the pigments. The peroxides used in the tooth bleaching systems or general whitening processes are known for ages in the industry of foods, textile, paper and others. In the industry, the bleaching reactions are optimized with the addition of catalysts, increase in the peroxide concentration and employment of appropriate temperatures so that several oxidation reactions occur simultaneously and within an appropriate time. In the case of dental bleaching, we cannot rely on temperature increase to accelerate the bleaching process. Therefore, the best way to

control the bleaching process is through the employment of the most adequate peroxide concentration (considering desirable results, available time and safety) and the inclusion of some catalytic system that might contribute to the bleaching process without causing any damage to the dental structure. The catalysis of the bleaching procedure can be obtained through the addition of chemical substances or by the use of external energy sources. In the last years, several external activation sources were indicated (or commercialized); however they have been questioned on their actual effectiveness and safety. On the other hand, one should not rule out the fact that time is a crucial factor in all bleaching stages and therefore can be considered as a determinant factor for the quality of the bleaching procedure. Attempts to reduce the time required for bleaching such as performing bleaching in a single clinical appointment and to provide even better results have been the challenge of the industry in the last years. However, one should consider that there are some limitations in the catalysis processes that are applicable to the dental bleaching and any drastic reduction in the application time, as it is proposed by some bleaching products, does not focus primarily on the quality of the bleaching result.

- In the last years there is an intensive search for acceleration processes for in-office vital tooth bleaching, focusing mainly on the development of equipments that supply ultrasound, blue or green light (LEDs or lamps), infrared LASERS and others. A common side effect to all bleaching modalities, the tooth sensitivity, is usually more intense when teeth are submitted to in-office bleaching. The tooth sensitivity caused by the dental bleaching is a biological reaction against the presence of hydrogen peroxide in the dental tissue. The intensity of the tooth sensitivity depends on the amount of hydrogen peroxide that achieves this tissue. There are cases in which the tooth sensitivity is limited to one or another tooth. The side effect is generally mild and intermittent, but may be intense and acute in some cases. The tooth sensitivity has been correlated with the presence of pre-existing enamel micro-cracks, which allow the penetration of great amounts of hydrogen peroxide in the dental structure in a short period of time.
- Considering the tooth sensitivity as a comfort parameter and as a safety limit manifested by the dental vitality, one cannot rule out the fact that we are likely in the limit of employing safe catalysis processes for in-office vital tooth bleaching. The use of external sources to accelerate even more the bleaching procedure can risk the vitality of the teeth. The current tendency nowadays is the use of lower hydrogen peroxide concentrations with chemical catalysis within viable application time.

6.2 Efficacy of the product

Traditionally in-office bleaching products contain hydrogen peroxide in concentrations that vary from 35 to 38%. This hydrogen peroxide concentration is used in order to achieve a desirable result within an appropriate clinical time. In order to ensure comfort for the patient and a viable bleaching protocol for the professional, the time of bleaching treatment should be limited.

Considering that it is highly desirable to have a short application time for the bleaching gels and taken into consideration the most recent tendency of increasing the safety in the bleaching process, without loss in effectiveness, FGM has developed a new formulation with a new catalytic system and release this product in a version containing lower hydrogen peroxide concentration (20%). Due to the higher activity of these bleaching gels, the application time was reduced and the process simplified. The chairtime required for the accomplishment of the bleaching procedure with bleaching gels that require changes every 15 minutes is approximately 1 hour, since the gel is usually refreshed three times in each session (3 x 15 minutes), and there is the time involved in the aspiration of the bleaching gel, preparation of the new portion and re-application. The 35% Whiteness HP Blue requires 40 minutes in contact with the tooth structure while the 20% HP Blue requires 50 minutes. The reduction in the application time and the hydrogen peroxide concentration (20%), allowed the reduction of the tooth sensitivity during and after the bleaching treatment without any loss in the effectiveness of the product.

6.3 The Presence of Calcium in the Formulation

The effects of the bleaching gels on the dental structure have been the aim of several studies. Among them, it is important to mention the increase in the superficial roughness and the drop in the enamel microhardness. These findings have been attributed to the removal of calcium from the dental surface by the bleaching gel due to the presence of peroxide stabilizers that remove it from the surface, to bleaching gel acidity or also by the simple disaggregation of the superficial layer that covers the dental structure (superficial cleaning). Therefore, it is reasonable to hypothesize that the addition of calcium in the dental bleaching system could minimize these detrimental effects. Being the bleaching gel saturated with calcium, this product would not remove more calcium from the dental structure.

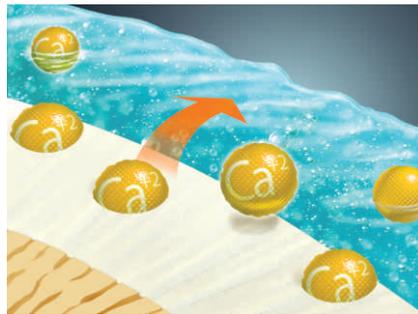
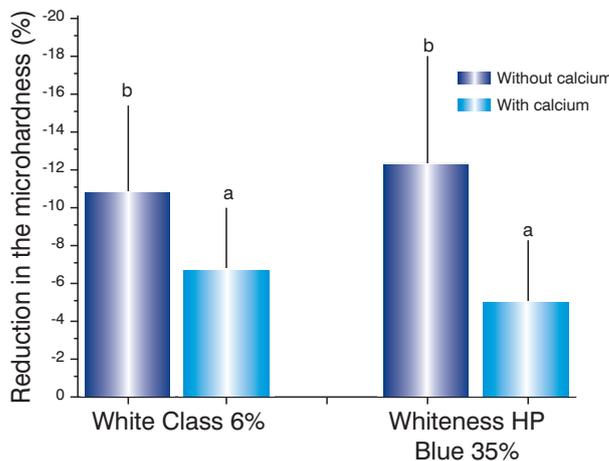


Figure 1: Bleaching gel without calcium: Tooth presenting greater calcium concentration than the gel. In this case there is a tendency of calcium ions migration from the tooth to the gel, balancing the concentration.



Figure 2: Bleaching gel with calcium: Reduction or absence of different calcium concentration between tooth and gel, consequently minimizing the demineralization process.

Whiteness HP Blue contains after mixture of the phase, 2% calcium gluconate, which is extensively used in the pharmaceutical industry as a source of calcium replacement for the organism. Comparative results between bleaching gels with and without calcium are depicted below and they clearly demonstrate the beneficial effects of calcium in the bleaching gel formula.



Graphic 1 - Reduction in the enamel microhardness after treatment with 35% Whiteness HP Blue and 6% White Class (FGM) with and without calcium. The values depicted in the graphic are in percentage and they are statistically different. Study conducted in UNICAMP – Prof. Dr. Marcelo Giannini.

By looking at the graphic one should notice that for both bleaching systems, the reduction in the enamel microhardness was significantly lower when calcium was incorporated in their formulation. The enamel microhardness reduction for Whiteness HP Blue with calcium reached values lower than what was observed for 6% White Class product.

Source: Prof. Dr. Marcelo Giannini – UNICAMP – SP

7. Mode of Use

General Information

Bland dental staining can be removed in a single bleaching appointment. However, there are some cases that require more than one clinical bleaching session. This is highly dependent of the etiology and age of the discoloration.

If after two 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 one more clinical session, with at least a 7-day interval between each appointment.

In cases which the patient present teeth with a high level of hipersensitivity, it's recommended the use of HP Blue 20% and also the application of desensitizers such as Desensibilize KF2% or KF0,2%. 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 (Whiteness Perfect 10%, for instance).

Similarly to the other bleaching techniques, it is highly recommended to record the shade before the treatment beginning, to instruct the patient regarding the case prognostic (limitations in case of tetracycline staining, teeth with grayish shades, etc.), to inform the patient about the likely tooth sensitivity and the need of restorations replacement. Some teeth may not meet desired expectations because of unforeseen factors, peculiar enamel features or type of staining.

Precautions and Contra-Indications

- 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.
- 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.
- The product does not require the use of any activation light source (LASERs, quartz-tungsten halogen lights or LEDs). The temperature in the pulpal tissue must not exceed 42 °C in order to avoid irreversible damage to its vitality.
- Enamel acid etching before the application of the bleaching gel is not recommended.
- While handling the product, the professional as well as the assistant should wear protective gloves and eyewear compatible with the equipment type to be employed. 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. Avoid prolonged contact of the product with lips, cheek, tongue, palatum and gingival tissue.
- 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 following all safety measures and personal protection described above.
 - 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 (Arcflex). 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 acidic drinks 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.
 - 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 later). 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.

Product's Application



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



2. Perform tooth prophylaxis with pumice and water



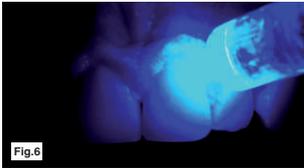
3. Determine and record the shade with a shade guide before bleaching and take a picture to record the initial appearance of the case.



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.



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 application of the gingival barrier and bleaching gel.



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.



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.



8. Twist an application tip in the syringe with the bleaching gel and apply Whiteness HP Blue 0.5–1mm layer on the buccal surfaces (including the interproximal areas) of the 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 is enough for simultaneous application in both dental arches.



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 are 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.



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.



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

8. 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 later). 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.

9. Conservation and Storage

Store the product at temperature between 5 e 25°C. Do not freeze the product. Keep out of direct sunlight.

The information described in the technical profile is based on the current state of knowledge. Being unable to know all of the applications for which our products may be applicable and their conditions of use, liability cannot be accepted for damages resulting from a particular application. Besides that, the information contained in the technical profile must not substitute any preliminary testing for the material suitability and use for any purpose not explicitly stated in the Instructions. The user is responsible to determine if the material described herein is suitable to another purpose than the stated in the Instructions.

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ZANIN, F., BRUGNERA, Junior A. Clareamento Dental com Luz – Laser - Capítulo 1 – 2ª Edição – Editora Santos

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