

### INSTRUCTION FOR USE DENTIST

ENA®WHITE 2.0 is a cosmetic tooth bleaching system.

It uses a 6% hydrogen peroxide-based whitening gel equipped with a special XS151 accelerator that is activated by brushing thus increasing exponentially, the rate of peroxide absorption compared to a traditional whitening. It is a highly viscous transparent blue colour with a mint flavour.

It consists of two phases, the first outpatient performed by the chairside dentist according to protocol, and one at home, continued by the patient with the special ENA®WHITE 2.0 toothbrush equipped with a dispenser that is filled with enough whitening gel for a treatment of about 20 days with two daily 2-minute applications, to be repeated for another 20 days, after further refill.

### INDICATIONS

Active cosmetic tooth bleaching that is particularly effective on healthy teeth.

Statistically found to be most effective in young patients.

The effectiveness of whitening may be limited or impaired in cases of:  
pathogenic and/or iatrogenic discolouration - thin and/or very gray enamel

### INSTRUCTIONS FOR USE - OUTPATIENT OPERATING PROTOCOL.

- A) Thorough hygiene session including scaling and enamel cleaning on the anterior teeth - upper and lower arch smile line - with scaler
- B) Bicarbonate application with Smart Prophy Pink toothbrush (fig. a), moistened, mounted on contra-angle (200/250 rpm) for 2/3 min total in order to prepare teeth for whitening gel.
- C) Application of Ena®White 2.0 gel, evenly over the entire surface of the teeth to be treated: leave on for 10/15 min (fig. b)
- D) Innovative treatment of the anterior teeth, with whitening gel using a dry Smart Prophy Pink brush, mounted on a contra-angle, (max 300/400 rpm to avoid dispersion of the gel outside the tooth) for about 30/40 seconds on each tooth (fig. c). This procedure results in greater penetration of the 6% hydrogen peroxide into the tooth by increasing the concentration of active oxygen resulting in increased whitening action
- E) Removal of residual gel with water jet and rinsing
- F) Checking the whitening effect with the patient (Fig. d).
- G) Delivery of the Ena®White 2.0 toothbrush to the patient with first application made in the office under the supervision of the dentist (see next points). The toothbrush has a reservoir that should be filled with the whitening gel contained in the syringe (enough for two refills for a treatment of about 20 days each).

### FIRST REFILL

- 1) Store the syringe in the fridge until the first use.
- 2) When the first treatment is performed, take the syringe from the fridge and remove the small cap on the syringe tip; keep it in order to cap the syringe again (pic. 1).
- 3) After removing the cap open the toothbrush and unscrew the head from the dispenser (pic. 2).
- 4) Push the silicon disc using the syringe tip (pic. 3) until it reaches the bottom of the dispenser.
- 5) Inject the gel into the dispenser until only 5 ml of gel remain into the syringe; always leave the syringe tip into the gel in order to avoid any bubbles (pic. 4-5). Cap the syringe again and place it in the fridge.
- 6) Screw the head of the toothbrush on the dispenser (pic. 6) (the special head GUM CARE™ of reduced size limits the risk of contact with gingival tissue), rotate anti-clockwise the ring on the base of the toothbrush towards the direction "UP" until the gel is coming out from the hole between the bristles. It is necessary a dose like the volume of a small lentil (pic. 7). Instruct the patient to use the product performing the first treatment with him.

For the daily treatment the patient will have to:

- take out from the fridge the toothbrush ENA®WHITE 2.0 and unscrew the cap.
- rotate anti-clockwise the ring on the base of the toothbrush towards the direction "UP" until a quantity of gel like a small lentil is coming out (after the first application it will be sufficient to rotate the ring of 2-3 marks ), then brush the teeth for about 30 seconds avoiding to brush the gums (pic. 8).
- rinse the toothbrush with water (pic. 9) and brush again the teeth for other 30 seconds (pic. 10), then rinse carefully the mouth with water as usual. *NOTE. The application times indicated are sufficient for a treatment limited to the 6 upper central teeth. In case that also lower teeth must be bleached it is necessary to increase the brushing time of about 15 seconds.*

- screw the cap of the toothbrush. In order to avoid gel spilling, especially during transport, slightly rotate the ring towards the direction "DOWN".

- repeat for 2-3 times per day, preferably after oral hygiene (it is recommended to use the toothpaste Enamel Plus, with low abrasion formula, desensitizing and tooth-whitening action and the IF Interdental Floss of the Ena®Oral Care line). The innovative packaging allows to perform the treatment even when not at home, in the office, at the gym using previously the Digital Brush towel to clean the teeth. After showing the treatment to the patient, the product can be delivered with the enclosed instructions.

The patient must be informed about the necessity to reduce the intake of food and beverages, which have the increased capacity to cause discolouration, the number of cigarettes and all the habits that can negatively influence the treatment efficacy. Moreover, the patient should be made aware of possible transient episodes of hypersensitivity; if these become particularly annoying, the treatment should be temporarily suspended.

### SECOND REFILL

- 7) When the patient comes back for a check after 20 days, check the colour (the patient must bring the empty toothbrush). In case the patient requires further bleaching effect, proceed as follows:
- 8) Take the syringe with the remaining 5 ml from the fridge and remove the cap.
- 9) Open the patient's toothbrush after removing the cap and unscrew the head from the dispenser. Rotate the ring towards the direction "DOWN" until the piston reaches the bottom of the dispenser (pic. 11).
- 10) Push the silicon disc of the dispenser using the syringe tip (pic. 12) until it reaches the bottom of the dispenser (pic. 13).
- 11) Inject the gel into the dispenser until the content of the syringe finishes; always leave the syringe tip into the gel in order to avoid any bubbles (pic. 14).
- 12) Screw the same head (which contains the residual gel) on the dispenser and give the toothbrush back to the patient.

*NOTE: In case the patient does not need further bleaching, the remaining refill of 5 ml can be used for the same patient later, or for another patient for a third treatment of 20 days; as a residual of the gel of the previous refill remains into the head, always check the expiry date indicated on the toothbrush before refilling. In order to avoid any contamination, always use a new syringe for the first refill, and a syringe which has already been opened for the second or third refill.*

### THE RECOMMENDED AVERAGE CYCLE OF TREATMENT IS:

1/2 minutes twice or three times a day, until finishing the dispenser contents, it is sufficient for a treatment of 2/3 weeks.

### PRECAUTIONS-WARNINGS

1. Not to be used on a person under 18 years of age.
2. To be only sold to dental practitioners. For each cycle of use, the first use to be only done by dental practitioners or under their direct supervision if an equivalent level of safety is ensured. Afterwards ENA®WHITE 2.0 can be delivered to the patient to complete the cycle of use.
3. Please note the expiration date printed on the package indicated by the hourglass symbol (month/year).
4. Avoid contact with eyes; rinse immediately for several minutes if product comes into contact with them. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice. The use of peroxide can give rise to a series of problems, the more common being dentine hypersensitivity and irritation of the mucosa; it is therefore contraindicated in the presence of certain conditions, as listed below:

- Exposed dentine areas • Pregnancy • Presence of gingival inflammation
- Presence of extensive caries • Presence of amalgam restorations in the anterior teeth (possible grey colouration caused by the chemical reaction peroxide-silver)
- Defected filling margins • Dental hypersensitivity

A certain reduction in the micro-hardness of enamel, after treatment with hydrogen peroxide, has been recently observed, which nevertheless, returns to its initial condition, thanks to the remineralisation process commencing immediately after treatment. Topical application of a fluoride gel (ie Ena White desensitizing gel) which progressively re-mineralises the enamel is indicated to reduce the phenomenon of pulpal sensitivity.

Finally, it was noted that treatments with hydrogen peroxide condition the possibility of performing an adhesive restoration, since they affect the presence of residual free radicals on the surface of

