

## Directions for Use

### In Office Bleaching Gel 27% Hydrogenperoxide

#### Instruction for dentists

#### Product description

**Oxford Double BLEACH** is a self-activating 27% hydrogen peroxide containing bleaching material in a 10:1 MINIMIX-syringe.

#### Please Note:

Tooth whitening products are only to be sold to dental practitioners. The use of the product must be administered by dental practitioner who will have performed a clinical examination. Not to be used on a person under 18 years.

**Composition:** hydrogenperoxide, glycerin, activator

#### Indications:

Whitening of individual or multiple discolored teeth (vital and non-vital) within a dental treatment. Teeth whitening takes place by oxidative breakdown of organic substances in the enamel.

**A medical dental treatment with Oxford Double BLEACH may be necessary at:**

#### External bleaching

- discoloration caused by medication (e.g. tetracycline or minocycline)

#### Intra coronal bleaching

- pulp nekrosis and/or consequences of endodontic treatments

External bleaching with Oxford Double BLEACH is also possible at:

- age-dependent discolorations
- food-related discolorations (e.g. coffee, tea, tobacco, red wine)

#### Performance features

The performance features of the product meet the requirements of the intended use.

#### Contraindications:

Do not use **Oxford Double BLEACH** in the case of:

- pregnant or lactating women
- patients known to be allergic to any of the ingredients
- heavy smokers, except in the case, they don't smoke during the duration of the treatment
- in the presence of teeth which are cervical exposed
- in the presence of crowns and bridges with marginal gaps
- in the presence of untreated caries
- periodontal diseases
- hypersensitive patients

Discontinue treatment if the patient experiences excessive pain sensation.

#### Patient target group

Persons who are treated during a dental procedure.

#### Intended users

This medical device should only be used by a professionally trained dental practitioner.

#### Warnings:

- hydrogenperoxide-contact with the skin, the mucous membrane or with eyes causes irritation. In the case of contact rinse with plenty of water and consult an ophthalmologist (contact with eyes)
- do not swallow
- keep out of reach of children

#### Hints:

Tooth and gingiva may be sensitive to the bleach gel, in this case reduce the amount of gel used and /or reduce the gel contact-time to tooth. If the symptoms continue check the patients allergy to the bleach ingredients. It might be necessary to discontinue the treatment.

#### Application:

##### External bleaching

1. Ensure that the teeth are cleaned thoroughly.
2. Mask the gingiva with Oxford Dam according to the corresponding instructions or protect the gingiva by rubber dam.
3. Oxford Double BLEACH is applied through the mixing tip directly onto the teeth. Before applying discard the first amount (approx. the size of a pea) of the extruded material. Agitate with a dental brush to enhance bleaching activity.
4. After an exposure time up to 20 minutes remove the bleaching gel by using gauze or a brush and rinse well with water.
5. Remove the gingiva protection.
6. If desired, a fluoridation treatment could be accomplished.
7. Use for every new application a new mixing cannula (the mixed material in the mixing cannula will become ineffective for bleaching purposes after some time).
8. For storage remove the mixing cannula and replace the cap.

Steps 3 and 4 can be repeated twice per visit. If additional bleaching is desired, repeat treatment is possible after one week.

For sensitive-reacting patients reduce the application time or stop if it's too much sensitivity.

Please check the condition of the teeth and the gingiva during the whole bleaching treatment.

#### Intra coronal bleaching

1. Before starting the bleaching procedure take an X-ray to verify that the root canal filling is closely sealed.
2. First open the entrance to the pulp chamber and to the root canal and remove carefully existing filling material. Ensure that enough space is created in the area of the coronal pulp to accommodate the bleaching gel.  
The root canal filling should be removed to a maximum depth of ca. 2 mm below the cervical gingival and should afterwards be tightly covered with a lining material.  
**Warning:** Remove all carious dentine before application of the bleaching gel!
3. Create a dry working area around the affected tooth. Use a rubber dam is recommended to provide adequate protection against inhalation or swallowing of the highly reactive bleaching gel. For alternative protection of the gingiva apply Oxford Dam according to the corresponding instructions.
4. Fill Oxford Double BLEACH into the cavity and leave enough space for the temporary restoration. Leave the bleaching gel- depending on the degree of discoloration - up to 3-5 days in the cavity.  
**Note:** For storage remove the mixing cannula and replace the cap.
5. During the exposure time of Oxford Double BLEACH seal the cavity with a classical glass ionomer cement (e.g. Oxford GI FILL). Verify occlusal clearance in protrusive and laterotrusion movements. Premature occlusal contacts may fracture the provisional restoration resulting in leakage and loss of bleaching gel with subsequent damage of the mucosa. Instruct the patient to contact a dentist if he feels a leakage or something unusual.
6. After the exposure time remove the bleaching gel carefully from a cavity using a surgical suction cannula.
7. To increase the bleaching effect, step 5 to 7 can be repeated twice.
8. When the tooth has reached the desired shade, remove the bleaching gel and rinse the cavity thoroughly with plenty of water.
9. Seal the cavity with a suitable temporary filling material. The filling should remain in situ for at least 14 days before a definitive treatment with a composite is possible.

#### Patient Information:

- In the first two weeks after bleaching teeth may darken slightly. Restorations can be replaced two weeks after finishing the bleaching treatment.
- To reduce the risk of discoloration, avoid staining foods, beverages and tobacco for 24-48 hours after treatment.

#### Storage:

Store **Oxford Double BLEACH** in the **refrigerator at 2-6°C (36-43 °F)** to maintain the gel-like consistency. (keep out of sunlight and heat!)

#### Disposal

Disposal of the product according to local authority regulations.

#### Reporting obligation

Serious incidents according to the EU Medical Devices Regulation that have occurred in connection with this medical device must be reported to the manufacturer and the competent authority.

#### Dentist Information:

- Before each application check the consistency of the material.
- First Scientific Dental Materials GmbH only recommends for Oxford Double BLEACH the use of mixing cannulas type Oxford Mix TIP(S)08.
- DoubleBleach is not for laser activated bleaching.

#### Warranty

First Scientific Dental Materials GmbH warrants this product will be free from defects in material and manufacture. First Scientific Dental Materials makes no other warranties including any implied warranty of merchantability or fitness for a particular purpose. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusively remedy and First Scientific Dental Materials' sole obligation shall be repair or replacement of the First Scientific Dental Materials product.

#### Limitation of Liability

Except where prohibited by law, First Scientific Dental Materials GmbH will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

#### Caution:

**Federal law restricts the sale of this device to or by the order of a dentist.**

