

Protective Sealant for Treatment of Hypersensitive Dentin

TOKUYAMA SHIELD FORCE PLUS**ENGLISH**

Read all information, precautions and notes before using.

PRODUCT DESCRIPTION AND GENERAL INFORMATION

1. TOKUYAMA SHIELD FORCE PLUS is a one-component, single application, light-cured protective sealant designed for the treatment of hypersensitive dentin. TOKUYAMA SHIELD FORCE PLUS effectively infiltrates and seals exposed dentinal tubules to inhibit the flow of fluid through the tubules which is the cause of sensitivity. At the same time the durable coat of cured TOKUYAMA SHIELD FORCE PLUS helps prevent loss of dentin due to abrasion and/or erosion of exposed cervical dentin.
2. A light-curing unit with a wavelength range of 400 to 500 nm (peak: 470 nm) may be used for curing TOKUYAMA SHIELD FORCE PLUS.
3. TOKUYAMA SHIELD FORCE PLUS contains phosphoric acid monomer, bisphenol A di(2-hydroxy propoxy) dimethacrylate (Bis-GMA), triethylene glycol dimethacrylate, 2-hydroxyethyl methacrylate (HEMA), camphorquinone, alcohol and purified water. The pH level immediately after dispensing is approximately 2.0.
4. TOKUYAMA SHIELD FORCE PLUS is dispensed in a bottle.

INDICATIONS

TOKUYAMA SHIELD FORCE PLUS is indicated for:

- Treatment of hypersensitive dentin,
- Reduction of abrasion and erosion of exposed cervical dentin,
- Alleviation and/or prevention of tooth sensitivity after tooth preparation for direct and indirect restorations.

CONTRAINDICATIONS

- 1) TOKUYAMA SHIELD FORCE PLUS contains methacrylic monomers, organic solvents and acids. DO NOT use TOKUYAMA SHIELD FORCE PLUS for patients allergic to or hypersensitive to methacrylic monomers, related monomers, organic solvents and acids.
- 2) TOKUYAMA SHIELD FORCE PLUS is NOT indicated for:
 - Treatment of subgingival area where the gingival reattachment is expected,
 - Direct pulp capping,
 - Root canal sealing.
- 3) Not to be used if the patient suffers from severe gingival inflammation (especially conditions which can lead to tissue sloughing, e.g. acute necrotizing ulcerative gingivitis (ANUG)).

PRECAUTIONS

- 1) DO NOT use TOKUYAMA SHIELD FORCE PLUS for any purposes other than those listed herein. Use TOKUYAMA SHIELD FORCE PLUS only as directed.
- 2) TOKUYAMA SHIELD FORCE PLUS is designed for sale and use by licensed dental care professionals only. It is not designed for sale nor is suitable for use by non-dental care professionals.
- 3) DO NOT use TOKUYAMA SHIELD FORCE PLUS if the safety seals are broken or appear to have been tampered with.
- 4) If TOKUYAMA SHIELD FORCE PLUS causes an allergic reaction, discontinue its use immediately.
- 5) Use examination gloves (plastic, vinyl or latex) at all times when handling TOKUYAMA SHIELD FORCE PLUS to avoid the possibility of allergic reactions from methacrylic monomers. Note: Certain substances/materials may penetrate through examination gloves. If TOKUYAMA SHIELD FORCE PLUS comes in contact with the examination gloves, remove and dispose of the gloves, and wash hands thoroughly with water as soon as possible.
- 6) Avoid contact of TOKUYAMA SHIELD FORCE PLUS with eyes, mucous membrane, skin and clothing.
 - If TOKUYAMA SHIELD FORCE PLUS comes in contact with the eyes, thoroughly flush eyes with water and immediately contact an ophthalmologist.
 - If TOKUYAMA SHIELD FORCE PLUS comes in contact with the mucous membrane, wipe the affected area immediately, and thoroughly flush the area with water. Affected areas may be whitened from protein coagulation, but such whitening tissue should disappear within 24 hours. If such whitening does not disappear after 24 hours, immediately contact a physician, and the patient should be so advised.
 - If TOKUYAMA SHIELD FORCE PLUS comes into contact with the skin or clothing, immediately saturate the area with alcohol-soaked cotton swab or gauze.
 - Instruct the patient to rinse his/her mouth immediately after treatment.
- 7) TOKUYAMA SHIELD FORCE PLUS should not be ingested or aspirated. Ingestion or aspiration may cause serious injury.
- 8) To avoid the unintentional ingestion of TOKUYAMA SHIELD FORCE PLUS, do not leave it unsupervised within the reach of patients and children.
- 9) DO NOT expose TOKUYAMA SHIELD FORCE PLUS or its vapor to open flame because TOKUYAMA SHIELD FORCE PLUS is flammable.
- 10) To avoid cross infection, DO NOT reuse the disposable applicator included in the TOKUYAMA SHIELD FORCE PLUS package.
- 11) Clean the dispensing well included in the TOKUYAMA SHIELD FORCE PLUS package thoroughly with alcohol after each use.
- 12) When using a light-curing unit, protective eye shields, glasses or goggles should be worn at all times.

PRECAUTIONS FOR MEDICAMENTS AND MATERIALS

- 1) Some materials and medicaments (hemostatic solutions) inhibit curing of TOKUYAMA SHIELD FORCE PLUS for an extended period even after meticulous cleansing with water. DO NOT USE products which contain:
 - Eugenol
 - Hydrogen peroxide
 - Sodium hypochlorite
 - Diammine silver fluoride [molecular formula: Ag(NH₃)₂F]
 - Phenols such as parachlorophenol, 2-methoxyphenol, phenol
 - Aluminum chloride
 - Ferric sulfate
 - Aluminum sulfate
 - Epinephrine
- 2) Application of phosphoric acid followed by application of TOKUYAMA SHIELD FORCE PLUS may reduce treatment efficacy.

STORAGE

- 1) Store under refrigerated conditions at temperatures between 0 to 10°C (32 to 50°F).
- 2) Keep away from heat, direct sunlight, sparks, and open flames.
- 3) DO NOT use after the indicated expiration date on the bottle/package.

DISPOSAL

Unused TOKUYAMA SHIELD FORCE PLUS is to be absorbed into an inert absorbent material such as gauze or cotton, and disposed of in accordance with local regulations.

CLINICAL PROCEDURES**1. Treatment of dentinal hypersensitivity****1.1. Cleaning**

Clean tooth surface and remove plaque and saliva with a cotton pellet. A rubber cup with a fluoride-free paste under local anesthesia may also be used to clean.

1.2. Isolation

The rubber dam is the preferred method for isolation.

1.3. Drying

Dry the tooth by using a blotting technique or an air syringe technique.

- DO NOT desiccate the hypersensitive dentin. Desiccation can aggravate the hypersensitivity.
- Glass ionomer lining or calcium hydroxide should be applied if the area to be treated is in close proximity to the pulp. DO NOT USE EUGENOL BASED MATERIALS to protect the pulp as these materials will inhibit curing of TOKUYAMA SHIELD FORCE PLUS.

1.4. Dispensing

Open the bottle cap and dispense one or two drops of sealant into the Dispensing Well. Close the bottle cap tightly immediately after dispensing.

- Wipe off the excess sealant on the tip of nozzle before closing.
- Do not mix the sealant with other materials.

1.5. Application

Apply generous amounts of the sealant to the area to be treated using the disposable applicator. Leave undisturbed for 10 seconds or more. If the excess sealant pools on the area, blot the excess with a new disposable applicator.

- Protect the dispensed sealant and the inserted applicator from ambient light before the application using a light blocking plate.
- Complete the application within 5 minutes after dispensing because TOKUYAMA SHIELD FORCE PLUS contains a volatile alcohol.
- If saliva, blood, or other fluids contaminate the applied area, thoroughly rinse the area with water, dry and re-apply the sealant.
- Do not rinse the applied sealant with water except in unintentional contamination.

1.6. Air Dry

Using an oil-free air/water syringe, apply weak air flow continuously to the sealant surface until the runny sealant stays in the same position without any movement (usually for 5 seconds). Finish by using a strong air flow for 5 seconds or more. Use a vacuum aspirator to prevent spatter of the sealant.

- If spattering accidentally occurs, it may cause the tissue to whiten or a possible allergic reaction.
- To prevent spattering, refer to the following tips:
 - 1) To avoid inadvertent strong air;
 - a) Be sure to begin with a weak air flow outside the mouth,
 - b) Direct the air flow at the applied area.
 - 2) Extending the distance of the air/water syringe from the tooth reduces the air flow. The mirror reflection technique is also useful in reducing the air flow.

1.7. Light-cure

Keep the curing light tip within a distance of 2 mm from the surface. Then light-cure the surface for 10 seconds or more. If the surface is too large, divide the area into segments and light-cure each segment individually.

- Confirm that the light-curing unit has sufficient intensity (>300 mW/cm²) before using. Note that using a cracked light guide will lower the intensity.

1.8. Check for excess material

Check for excess material in the gingival sulcus, and remove the excess with a scaler or periodontal curette. Instruct the patient to rinse his/her mouth immediately after treatment.

1.9. Test for sensitivity

If a single application of TOKUYAMA SHIELD FORCE PLUS does not sufficiently relieve the hypersensitivity or sustained pain persists, the treatment can be repeated before alternative treatments are indicated. If hypersensitivity persists after a second application, seriously consider other sources of pain, such as traumatic occlusion, pulpal pathology.

- If additional restorations are required due to the esthetic reason, restore according to procedures in step "2.9. Adhesive treatment" and "2.10. Composite resin filling".

1.10. Patient recall

Depending on individual oral hygiene, wear of the TOKUYAMA SHIELD FORCE PLUS may require re-application approximately every six months.

2. TOKUYAMA SHIELD FORCE PLUS sealant under direct restorations to alleviate and/or prevent tooth sensitivity after tooth preparation**2.1. Cleaning**

Thoroughly clean the tooth surface using a rubber cup with a fluoride-free paste then rinse with water.

2.2. Isolation

The rubber dam is the preferred method for isolation.

2.3. Cavity preparation

Prepare the cavity and rinse with water. Add bevels to the enamel margins of anterior preparations (class III, IV, V), as well as chamfers to the margins of posterior preparations (class I, II) because bevels and chamfers assist in masking demarcations between the cavity margins and the restoration, enhancing both esthetics and retention.

2.4. Drying

Dry the cavity by using a blotting technique or an air syringe technique.

- DO NOT desiccate the vital tooth. Desiccation can lead to post-operative sensitivity.
- Glass ionomer lining or calcium hydroxide should be applied if the area to be treated is in close proximity to the pulp. DO NOT USE EUGENOL BASED MATERIALS to protect the pulp as these materials will inhibit curing of TOKUYAMA SHIELD FORCE PLUS.

2.5. Dispensing

Open the bottle cap and dispense one or two drops of sealant into the Dispensing Well. Close the bottle cap tightly immediately after dispensing.

- Wipe off the excess sealant on the tip of nozzle before closing.
- Do not mix the sealant with other materials.

2.6. Application

Apply generous amounts of the sealant to the area to be treated using the disposable applicator. Leave undisturbed for 10 seconds or more. If the excess sealant pools on the area, blot the excess with a new disposable applicator.

- Protect the dispensed sealant and the inserted applicator from ambient light before the application using a light blocking plate.
- Complete the application within 5 minutes after dispensing because TOKUYAMA SHIELD FORCE PLUS contains a volatile alcohol.
- If saliva, blood, or other fluids contaminate the applied area, thoroughly rinse the area with water, dry and re-apply the sealant.
- Do not rinse the applied sealant with water except in unintentional contamination.

2.7. Air Dry

Using an oil-free air/water syringe, apply weak air flow continuously to the sealant surface until the runny sealant stays in the same position without any movement (usually for 5 seconds). Finish by using a strong air flow for 5 seconds or more. Use a vacuum aspirator to prevent spatter of the sealant.

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 - 1) To avoid inadvertent strong air;
 - a) Be sure to begin with a weak air flow outside the mouth,
 - b) Direct the air flow at the applied area.
 - 2) Extending the distance of the air/water syringe from the tooth reduces the air flow. The mirror reflection technique is also useful in reducing the air flow.

2.8. Light-cure

Keep the curing light tip within a distance of 2 mm from the surface. Then light-cure the surface for 10 seconds or more. If the surface is too large, divide the area into segments and light-cure each segment individually.

- Confirm that the light-curing unit has sufficient intensity (>300 mW/cm²) before

using. Note that using a cracked light guide

2.9. Adhesive treatment

Immediately apply adhesive as described in - If using a total etch adhesive system, DO use of TOKUYAMA SHIELD FORCE PLUS

2.10. Composite resin filling

Place the restorative material over the cure directions for use.

3. TOKUYAMA SHIELD FORCE PLUS sealant to alleviate and/or prevent tooth sensitivity after tooth preparation**3.1. Temporary Restoration****3.1.1. Tooth Preparation**

Following tooth preparation, core build-restoration, clean enamel and dentin with rubber dam or other suitable isolation technique - DO NOT desiccate the vital tooth. Do not sensitivity.

- Glass ionomer lining or calcium hydroxide should be applied if the area to be treated is in close proximity to the pulp. DO NOT USE EUGENOL BASED MATERIALS to protect the pulp as these materials will inhibit curing of TOKUYAMA SHIELD FORCE PLUS.

3.1.2. Dispensing

Open the bottle cap and dispense one or two drops of sealant into the Dispensing Well. Close the bottle cap tightly immediately after dispensing.

- Wipe off the excess sealant on the tip of nozzle before closing.
- Do not mix the sealant with other materials.

3.1.3. Application

Apply generous amounts of the sealant to the area to be treated using the disposable applicator. Leave undisturbed for 10 seconds or more. If the excess sealant pools on the area, blot the excess with a new disposable applicator.

- Protect the dispensed sealant and the inserted applicator from ambient light before the application using a light blocking plate.
- Complete the application within 5 minutes after dispensing because TOKUYAMA SHIELD FORCE PLUS contains a volatile alcohol.
- If saliva, blood, or other fluids contaminate the applied area, thoroughly rinse the area with water, dry and re-apply the sealant.
- Do not rinse the applied sealant with water except in unintentional contamination.

3.1.4. Air Dry

Using an oil-free air/water syringe, apply weak air flow continuously to the sealant surface until the runny sealant stays in the same position without any movement (usually for 5 seconds). Finish by using a strong air flow for 5 seconds or more. Use a vacuum aspirator to prevent spatter of the sealant.

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3.1.5. Light-cure

Keep the curing light tip within a distance of 2 mm from the surface. Then light-cure the surface for 10 seconds or more. If the surface is too large, divide the area into segments and light-cure each segment individually.

- Confirm that the light-curing unit has sufficient intensity (>300 mW/cm²) before using. Note that using a cracked light guide will lower the intensity.

3.1.6. Dismissal

Wipe the oxygen inhibition layer with alcohol.

3.1.7. Impression Taking

Take impression with impression material as directed.

3.1.8. Temporary Cementing

Seat the temporary/provisional restoration (water-based cement) according to manufacturer's instructions. (gutta-percha) may also be used for temporary restorations. Do not use resin-based material (cement/filling) over TOKUYAMA SHIELD FORCE PLUS.

3.2. Permanent Restoration**3.2.1. Cleaning of Cavity/Abutment**

Remove temporary restoration, residual teeth to the tooth by ultrasonic scaler or other clean-up techniques. Contaminants from the tooth surface to be prepared in usual manner.

- Elements listed below, which inhibit the curing of TOKUYAMA SHIELD FORCE PLUS, should be removed from the tooth surface by thorough cleaning with alcohol, citric acid, EDTA, or the application of a fluoride-releasing agent before cementation.
 - 1) Silicone oil from fit check material
 - 2) Oil mist from handpiece
 - 3) Saliva, blood and exudates

3.2.2. Cementing

Cement the restoration with resin cement according to manufacturer's instructions.

- The use of multistep resin cements are recommended. Self-adhesive resin cements are not recommended.

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