

Primer to enhance bonding between ceramics, metal and resin

TOKUYAMA UNIVERSAL PRIMER

ENGLISH

Read all information, precautions and notes before using.

■ PRODUCT DESCRIPTION AND GENERAL INFORMATION

1. TOKUYAMA UNIVERSAL PRIMER is a primer containing adhesive components that interact with various kinds of prosthetic materials. TOKUYAMA UNIVERSAL PRIMER improves the bond strength of polymerizable resin materials (adhesive resin cement, acrylic resin and composite resin) to indirect restorative materials such as glass-ceramics (porcelain), oxide-ceramics (zirconia and alumina), metals (precious and non-precious) and resin materials including inorganic filler.
2. TOKUYAMA UNIVERSAL PRIMER contains MTU-6 (thiourea monomer), 3-methacryloxypropyltrimethoxysilane, phosphoric acid monomer, MAC-10, Bisphenol A di(2-hydroxypropoxy) dimethylacetyl (Bis-GMA), triethyleneglycol dimethylacetyl, 1,6-bis(methacryloyloxy)carboxylic acid (UDMA), ethanol and acetone.

■ INDICATIONS

Pretreatment of glass/oxide ceramics (porcelain, zirconia and alumina), metals/alloys (precious and non-precious) and resin materials including inorganic filler (composite materials) in preparation for bonding with polymerizable resin materials, such as:

- Bonding of inlays, onlays, crowns, bridges, veneers, cores, artificial teeth, orthodontic brackets etc.
- Repair of ceramic, metal and composite materials (including porcelain fused metals).
- Bonding of denture resin to metal base, clasp or attachment.
- Repair of denture with metal base, clasp or attachment.
- Bonding of opaque resin to a metal base in the fabrication of resin-faced stainless steel crowns.

■ CONTRAINDICATIONS

TOKUYAMA UNIVERSAL PRIMER contains methacrylic monomers, organic solvents and acids. DO NOT use TOKUYAMA UNIVERSAL PRIMER for patients allergic to or hypersensitive to methacrylic monomers, related monomers, organic solvents and acids.

■ PRECAUTIONS

- DO NOT use TOKUYAMA UNIVERSAL PRIMER for any purpose other than those listed in these instructions. Use TOKUYAMA UNIVERSAL PRIMER only as directed herein.
- TOKUYAMA UNIVERSAL PRIMER is designed for sale and use by licensed dental care professionals only. It is not designed for sale nor is it suitable for use by non-dental care professionals.
- DO NOT use TOKUYAMA UNIVERSAL PRIMER if the safety seals are broken or appear to have been tampered with.
- If TOKUYAMA UNIVERSAL PRIMER causes an allergic reaction or oversensitivity, discontinue its use immediately.
- Use examination gloves (plastic, vinyl or latex) at all times when handling TOKUYAMA UNIVERSAL PRIMER to avoid the possibility of allergic reactions from methacrylic monomers. Note: Certain substances/materials may penetrate through examination gloves. If TOKUYAMA UNIVERSAL PRIMER comes in contact with the examination gloves, remove and dispose of the gloves, and wash hands thoroughly with water as soon as possible.
- Avoid contact of TOKUYAMA UNIVERSAL PRIMER with eyes, mucosal membrane, skin and clothing.
- If TOKUYAMA UNIVERSAL PRIMER comes in contact with the eyes, thoroughly flush eyes with water and immediately contact an ophthalmologist.
- If TOKUYAMA UNIVERSAL PRIMER comes in contact with the mucosal membrane, wipe the affected area immediately, and thoroughly flush with water after completing the restoration. Affected areas may whiten from protein coagulation; however, whitening should disappear within 24 hours. If whitening does not disappear within 24 hours, immediately contact a physician, and the patient should be so advised.
- If TOKUYAMA UNIVERSAL PRIMER comes into contact with the skin or clothing, immediately saturate the area with an alcohol-soaked cotton swab or gauze and flush with water.
- Instruct the patient to rinse his/her mouth immediately after treatment.
- TOKUYAMA UNIVERSAL PRIMER should not be ingested or aspirated. Ingestion or aspiration may cause serious injury.
- To avoid the unintentional ingestion of TOKUYAMA UNIVERSAL PRIMER, do not leave it unsupervised within the reach of patients and children.
- DO NOT expose TOKUYAMA UNIVERSAL PRIMER or its vapor to open flame because TOKUYAMA UNIVERSAL PRIMER is flammable.
- To avoid cross contamination, DO NOT reuse the disposable applicators and clean the mixing-well with alcohol after each use.

■ NOTES FOR USE

- Do not mix the TOKUYAMA UNIVERSAL PRIMER with other brands of primers or adhesives.
- Complete the application within 5 minutes after dispensing because TOKUYAMA UNIVERSAL PRIMER contains volatile solvents.
- Be sure to hold the bottles of TOKUYAMA UNIVERSAL PRIMER A and B vertically when dispensing. Do not hold the bottle diagonally or horizontally while dispensing; this could cause the primer to flow back into the nozzle and become contaminated.
- Wipe off excess primer on the tip of the nozzle prior to closing.
- Close the bottle caps of TOKUYAMA UNIVERSAL PRIMER A and B tightly immediately after dispensing.
- DO NOT over apply. One or two applications of TOKUYAMA UNIVERSAL PRIMER are sufficient. Too thick of a layer may result in poor adhesion.
- Be sure to dry the surface after TOKUYAMA UNIVERSAL PRIMER is applied. Incomplete drying may result in poor adhesion.

■ STORAGE

- Store TOKUYAMA UNIVERSAL PRIMER under refrigeration at a temperature between 0 to 10 °C (32 to 50°F).
- Keep away from heat, direct sunlight, sparks and open flames.
- DO NOT use after the indicated expiration date on the bottle.

■ DISPOSAL

Absorb unused TOKUYAMA UNIVERSAL PRIMER into an inert absorbent material such as gauze or cotton, and disposed of in accordance with local regulations.

■ CLINICAL APPLICATION OF TOKUYAMA UNIVERSAL PRIMER FOR BONDING OF RESTORATIONS

- Preparing the adhesive surface**
- Ceramics other than Porcelain, and Composite materials**
Roughen the area by sandblasting (0.1 to 0.2MPa), air abrasion or grinding with a diamond bur using a slow speed to prepare the surface for adhesion. Thoroughly rinse and dry the surface.
- Porcelain**
DO NOT roughen the surface. Polish the area to prepare a clean and fresh surface for adhesion. Thoroughly rinse and dry the surface.
- When using the sandblaster or air abrasion, use at least 30 to 50 micron grid of alumina powder.**
- If unable to roughen or polish the adhesive surface, etch the area for adhesion with phosphoric acid then thoroughly rinse and dry.**
- The substances listed below inhibit adhesion and must be removed from the adhesive surface by mechanical cleaning or alcohol soaking. Clean the restoration after adjustment is complete.**
- Gypsum and investment**
- Silicone oil from fit check material**
- Oil mist from headpiece**
- Plaque, tartar, saliva, blood and exudate fluids**
- If necessary, protect the surface not being bonded with metal separator, paraffin film, Vaseline, etc.**
- Dispensing**
Allow TOKUYAMA UNIVERSAL PRIMER to reach room temperature prior to use. Open the bottle cap and dispense one drop of TOKUYAMA UNIVERSAL PRIMER A and B into the mixing well. Mix thoroughly with a disposable applicator.

■ Application

Using the disposable applicator, apply the mixed primer on the surface to be bonded and leave undisturbed for 10 seconds.

- Ensure primer covers all surfaces where the adhesive will be applied.
- DO NOT allow saliva, blood, oil, water etc. to come in contact with the surface to be bonded. If the treated surface is contaminated, thoroughly rinse with water, dry and re-apply primer.

■ Air dry

Using an oil-free air/water syringe, apply mild air to the surface. Use a vacuum aspirator to prevent spatter of the primer.

■ Bonding procedure

Proceed with the bonding procedure according to the manufacturer's instructions for the use of the adhesive materials.

■ CLINICAL APPLICATION OF TOKUYAMA UNIVERSAL PRIMER FOR INTRAORAL REPAIR RESTORATIONS WITH COMPOSITE RESIN

1. Preparing the adhesive surface

1.1 Ceramics other than Porcelain, and Composite materials

Bevel the margin if necessary. Roughen the area using air abrasion or grinding with a diamond bur using a slow speed to prepare the surface for adhesion. Thoroughly rinse and dry the surface.

1.2 Metal restorations

Roughen the area using air abrasion or grinding with a diamond bur using a slow speed to prepare the surface for adhesion. Thoroughly rinse and dry the surface.

1.3 Porcelain

Bevel the margin if necessary. DO NOT roughen the surface. Polish the area to prepare a clean and fresh surface for adhesion. Thoroughly rinse and dry the surface.

- When using air abrasion, use at least 30 to 50 micron grid of alumina powder.

- The substances listed below inhibit adhesion and must be removed from the adhesive surface by mechanical cleaning or alcohol soaking.

- Oil mist from headpiece

- Plaque, tartar, saliva, blood and exudate fluids

- If necessary, protect the surface not being bonded with metal separator, paraffin film, Vaseline, etc.

- Dispensing

Allow TOKUYAMA UNIVERSAL PRIMER to reach room temperature prior to use. Open the bottle cap and dispense one drop of TOKUYAMA UNIVERSAL PRIMER A and B into the mixing well. Mix thoroughly with a disposable applicator.

Using the disposable applicator, apply the mixed primer on the surface to be bonded and leave undisturbed for 10 seconds.

- Ensure primer covers all surfaces where the adhesive will be applied.

- DO NOT allow saliva, blood, oil, water etc. to come in contact with the surface to be bonded. If the treated surface is contaminated, thoroughly rinse with water, dry and re-apply primer.

■ Air dry

Using an oil-free air/water syringe, apply mild air to the surface. Use a vacuum aspirator to prevent spatter of the primer.

■ Bonding procedure

Proceed with the bonding procedure according to the manufacturer's instructions for the use of the adhesive materials.

■ TOKUYAMA UNIVERSAL PRIMER가 눈에 들어가면 물로 눈을 잘 씻어내고 즉시 안과 의사의 진단을 받아 주십시오.

■ TOKUYAMA UNIVERSAL PRIMER가 점막에 묻으면 해당 부위를 즉시 닦아내고 완전히 수복 치료를 끝낸 후 물로 잘 씻어 주십시오. 물은 부위는 단백질 응고로 인해 백색화될 수 있지만, 24시간 이내에 사라집니다. 24시간 이내에 백색화가 사라지지 않으면 즉시 의사의 진료를 받고, 지시에 따라 주십시오.

■ TOKUYAMA UNIVERSAL PRIMER가 피부나 옷에 묻으면 알코올을 묻힌 면봉이나 거즈로 해당 부위를 닦아내고, 물로 씻어 주십시오.

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