

INSTRUCTION FOR USE

INSTRUCTION MANUAL

Components: Bis-GMA, HEMA, acid-modified acrylate resin, ethanol, purified water and other additional ingredients. Packaging: 5 mL.

PROFILLER GEN8 - BOND 8TH GENERATION WITH FILLER

1- Description

PROFILLER GEN8 Bond 8th Generation With Filler is a self-etching, low-visibility, single-layer, single-bottle 8th generation universal adhesive designed to be used as an adhesive in light-curing restorative treatments. It shows excellent adhesion to dentin and enamel. When used, it provides exceptional integrity to cut/uncut enamel and dentin and in combination with light or dual-curing composite materials. When ready for use, the pH level is around 2.5.

Contains Bis-GMA, HEMA, acid-modified acrylate resin, ethanol, purified water and other additional ingredients.

Curing can be easily achieved using a light curing unit with a wavelength between 400 and 500 nm. (The recommended light intensity is 1200 mW/cm2, it is recommended to extend the curing time for devices with lower intensity.) Dental treatment involves a complex surgical procedure. The instructions provided in the user manual inside the box are not sufficient to perform the filling process. Such applications should be performed by specialist dentists who have received the necessary training in this field.

Classification of the product according to Product Type Standard EN ISO 4049:

Type 2 / Class II / Group 1

2- Usage area / Indications

- Bonding of light or dual cured composites to enamel/dentin:
- Cut/uncut enamel,
- Cut/uncut dentin,
- Fractured porcelain/composite repair.

3- Usage

Prepare the cavity and rinse with water.

Dry the cavity by drying method or air syringe. Do not dry the vital tooth. Drying may cause sensitivity after the procedure.

Open the bottle by removing the cap and add one or two drops of PROFILLER GEN8.

Close the bottle cap tightly immediately after application. Wipe off excess PROFILLER GEN8 from the tip of the nozzle before closing.

Apply PROFILLER GEN8 to the application surface using the disposable applicator and wait for 10 seconds or more at a distance of 2 mm. PROFILLER GEN8, make sure that the composite resin covers all surfaces on which it will be applied and protect the placed applicator from ambient light by using a light blocking plate.

Complete the process within 5 minutes. PROFILLER GEN8 contains a volatile alcohol. Using an oil-free air/water syringe, continuously apply gentle air to PROFILLER GEN8. Apply PROFILLER GEN8 until it remains motionless (usually 5 seconds).

4- Contraindications

If the patient is known to be allergic to any of the ingredients: application of the above materials is not appropriate. If an allergic reaction occurs, seek medical attention as appropriate, remove the product if necessary, and do not use this product on this patient in the future.

5- Side effects

Do not use in patients with hypersensitivity to its ingredients.

6- Warning

- Protect the product from light. Exposure to the clinic room may cause discoloration and curing.
- The product should not be swallowed or aspirated. Swallowing or aspiration will cause serious injury. Instruct the patient to rinse the mouth immediately after treatment.
- It is not intended for sale and is not intended for use other than dental care.
- DO NOT use if safety seals are broken or the bottle appears damaged.
- Read all information, precautions and notes before use.
- Check the expiration date and working condition of the product and packaging. Do not use products whose packaging has been opened, damaged and/or expired.
- If PROFILLER GEN8 causes an allergic reaction, hypersensitive reaction such as dermatitis or hypersensitivity on the skin, consult your physician.
- Always use examination gloves (plastic, vinylex or latex) when handling PROFILLER GEN8.
- Avoid contact of the product with eyes, mucosal membranes, skin and clothing as it may cause an allergenic reaction.
- Keep the product out of reach of children.
- Avoid looking into the curing light when using the light-curing unit, use protective eye shields, goggles or large type glasses.
- PROFILLER GEN8 is supplied in 5 gr bottle form. Products that are opened and left open may damage the material and design

PROMİDA DİŞ MALZEMELERİ SAN. TİC. LTD. ŞTİ. 75. YIL MAH. KÜÇÜK ORGANİZE SANAYİ 3. CADDE 6A ODUNPAZARI/ESKİŞEHİR	HIMG SERAMİK VE MEDİKAL KOMPOZİT SANAYİ VE TİCARET LİMİTED ŞİRKETİ
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characteristics.

- PROMİDA DİŞ MALZEMELERİ SAN. TİC. LTD. ŞTİ. will not accept any liability for any injuries/discomforts resulting from misuse of the product. Returns of products with damaged original packaging will not be accepted.
- Please use personal protective equipment such as mask, glasses and apron during the procedures.

7- Storage conditions

Store PROFILLER GEN8 at a temperature between 2-27°C. Shelf life at the specified temperatures is 36 months (3 years) from the date of production. AVOID direct light and heat contact for PROFILLER GEN8.

NOTE:

Our products are produced for use in dentistry. It is not suitable for use other than professional dentists. Since the use of the products is under the control of the user other than us, the user is completely responsible for the applications. We recommend using it in accordance with the information and warnings given in the instructions.

**** Disposal:** Products should be treated according to their biological hazards and disposed of in accordance with the country's legal regulations and hospital policies.

8- Symbols and Meanings:

LOT	Lot number	\sim	Manufacturing Date
REF	Catalog Number		Manufacturer
\sum	Use on time	×	Keep away from sunlight
\triangle	Warning, Consult the accompanying documents.	ī	Refer to the Instructions for Use.
2'C	Storage temperature range	C E ₂₂₉₂	Notified body
Ĵ	Store in dry place.		

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