

INSTRUCTION FOR USE



INSTRUCTION MANUAL

Components: 80% by weight of filler particles with a particle size range of 0.03 - 1.0 μm. BİS-GMA, UDMA, TEGDMA resins.

Packaging: 4 g + application tip

PROFILLER UNICOMP - UNIVERSAL COMPOSITE

1- Description

PROFILLER UNICOMP is a polymer-based dental restoration material. PROFILLER UNICOMP is a light-cured micro hybrid composite material designed to be used in universal restorations, both anterior and posterior. PROFILLER UNICOMP is a radiopaque composite activated by visible light. Our radiopacity value is equal to 7.54 mm equivalent aluminum thickness for the products.

It contains 80% by weight of filler particles with a particle size range of $0.03 - 1.0 \mu m$. PROFILLER UNICOMP's matrix consists of BİS-GMA, UDMA, TEGDMA resins.

Curing of PROFILLER UNICOMP can be easily achieved by using a light curing unit with a wavelength between 400 and 500 nm (highest cure: 470 nm). (The recommended light intensity is 1200 mW/cm2, it is recommended to extend the curing time for devices with lower intensity.) PROFILLER UNICOMP is traditionally supplied in a twist-up syringe.

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

Type 1 / Class II / Group 1

2- Usage area / Indications

- Direct universal restorations including the occlusal surface.
- Porcelain/composite repair
- Direct restorations: Direct restorations made using light-cured composites or compomers.
- Indirect restorations: Cavity dressing for pre-treatment purposes
- Indirect applications such as Inlay Onlay & Veneer
- Treatment of hypersensitivity and/or exposed root surfaces

3- Usage

5.1. Cleaning

A cavity that is not properly cleaned can negatively affect bond strength. Therefore, clean the tooth surface thoroughly with a brush and paste if necessary, then rinse with water.

5.2. Humidity Contro

To achieve better results whenever possible, avoid contamination of the treatment area with saliva or blood. (Rubber-dam is the preferred isolation method; saliva ejector and cotton rolls can also be used for the same purpose.)

5.3. Color Selection

Teeth are not monochrome, and the color reflected by a restorative material is affected by the thickness of the restorative. Therefore, when choosing a color, the color selection should be made by looking at the part of the scale that is most similar to the restoration thickness.

5.4. Preparation of the cavity

Prepare the cavity in the standard manner by removing any infected dentin.

5.5. Protection of the pulp

The exposed pulp and areas close to the pulp should be covered with a fast-setting calcium hydroxide material. There is no need to prime or base with cement. Do not use materials containing eugenol to protect the pulp.

5.6. Application of matrix tape and wedges

Where necessary, the application of matrix tape and wedges can reduce the amount of material consumed.

If preferred, the matrix can be placed after the etching and adhesive process of the tooth enamel.

5.7. Adhesive System

Perform your process with suitable adhesive material.

5.8. Adjusting Composite Filling

Remove the syringe cap. Pipe the cake onto the mixing pad/paper by turning the handle clockwise.

Recap the syringe immediately after squeezing.

Fill the area to be filled step by step (2mm layering) using a suitable placement tool.

5.9. curing

You can apply the cure by shining a light on the product in the application area from a distance of 2 mm, as recommended in Table 01. (You can perform the process using a blue light source (ISO 4049) in the 400-500 nm range.)

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HIMG SERAMİK VE MEDİKAL KOMPOZİT SANAYİ VE TİCARET LİMİTED SİRKETİ



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Model	Curing Thickness	Light Application Time
A1, A2, A3, B1, B2, B3, B4, C1, C2, A2O,BW,TR	2,4 mm	20 seconds
A4, C3, C4	2,4 mm	40 seconds

NOTE: The recommended light intensity is 1200 mW/cm2, it is recommended to extend the curing time in devices with lower intensity.

After the curing process is completed, shape the restoration surfaces with thin diamond finishing burs or stones. Ensure and check occlusion with a fine polishing bur or stone.

5.10. Polishing

Polish with a polishing system and with white stones or rubber tips in areas where the discs are not suitable for use.

4- Contraindications

PROFILLER UNICOMP contains methacrylic monomers. PROFILLER UNICOMP is contraindicated in patients who are allergic to or hypersensitive to methacrylic and related monomers.

5- Side effects

Do not use in patients with hypersensitivity to its ingredients.

6- Warning

- · Protect the product you have sprayed on the mixing pad/paper from light if you are not going to use it immediately.
- Do not apply PROFILLER UNICOMP together with other resin composites or shades to avoid incomplete curing or entrapment of bubbles.
- PROFILLER UNICOMP for any purpose other than the purposes stated in the instructions for use.
- Do not use products whose packaging has been opened, damaged and/or expired.
- PROFILLER UNICOMP causes an allergic reaction, hypersensitive reaction such as dermatitis or hypersensitivity on the skin, consult your physician.
- To avoid the possibility of allergic reactions caused by methacrylic monomers, always use examination gloves (plastic, vinyl or latex) when handling PROFILLER UNICOMP.
- PROFILLER UNICOMP should not be swallowed or inhaled.
- Keep the product out of reach of children.
- PROFILLER UNICOMP after the expiration date written on the syringe or package.
- Avoid looking into the curing light when using the light-curing unit, use protective eye shields, goggles or large type glasses.
- PROFILLER UNICOMP is supplied as a 5.0 gram syringe. Products that are opened and left open may damage the material and design 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.
- To dispose of the FILLER safely, squeeze the unused part of the syringe and cure with light before disposal.
- Please use personal protective equipment such as mask, glasses and apron during the procedures.
- The color coding of the products is made in accordance with the VITA Zahnfabrik color grading.

7- Storage conditions

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

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.

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8- Symbols and Meanings:

LOT	Lot number	\sim	Manufacturing Date
REF	Catalog Number		Manufacturer
23	Use on time	类	Keep away from sunlight
À	Warning, Consult the accompanying documents.	$\bigcap_{\mathbf{i}}$	Refer to the Instructions for Use.
2'C	Storage temperature range	C € ₂₂₉₂	Notified body
*	Store in dry place.		

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