

INSTRUCTION MANUAL

Components: 63% filler particles (0.100 – 0.900 microns, Dental Glass, YbF3), UDMA and acid-modified acrylate resins.
Packaging: 2 g.

PROFILLER FS - FISSURE SEALANT**1- Description**

PROFILLER FS Fissure Sealant is a polymer-based dental restoration material. It is designed to protect fissures against decay by creating a leak-proof layer. PROFILLER FS functions as a precaution against allowing food or bacteria to enter the fissure. Therefore, closing fissures plays an important role in preventing caries. The appearance of the product is a fluid, low viscosity paste of different colors that hardens after solidification.

PROFILLER FS is a radiopaque composite activated by visible light.

It contains 63% filler particles (0.100 – 0.900 microns, Dental Glass, YbF3) by weight. Its matrix consists of UDMA and acid-modified acrylate resins and does not contain Bis-GMA. 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.)

PROFILLER FS dental treatment involves a complex surgical procedure. The instructions provided in the user manual included in the box are not sufficient to perform the operation. Such applications should be performed by specialist dentists who have received the necessary training in this field.

PROFILLER FS 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

- Sealing/filling of pits and fissures
- Filling small bruises
- Filling milk teeth
- Sealing of margin leakage
- Temporary filling modifications and composite restorations repair.

3- Usage**a. Cleaning**

A cavity that is not properly cleaned can negatively affect bond strength. Clean teeth thoroughly to remove plaque and debris from enamel surfaces and cracks. Therefore, clean the tooth surface thoroughly with a brush and paste if necessary, then wash the teeth thoroughly with air/water spray and rinse with water to remove the abrasive substance.

b. Humidity Control

Remove the rinse water by suction and dry the worn surfaces. To achieve better results as much as possible, avoid saliva or blood contamination of the treatment area, isolate the treated teeth. (Rubber-dam is the preferred isolation method; saliva ejector and cotton rolls can also be used for the same purpose.) The tooth surface should be dried.

c. 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.

d. Preparation of the cavity

Prepare the cavity by removing any infected dentin.

e. 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.

f. 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.

g. Adhesive System

Perform your process with suitable adhesive material.

h. Adjusting Composite Filling

PROFILLER FS can be gently applied directly from the application tip to the prepared pit and fissure. It is recommended that the patient and staff wear protective glasses when using the application tip. Remove and retain the syringe cap. Attach the pre-bent disposable administration tip securely to the syringe. Keep the tip away from the patient and check whether the tip is clogged in order to apply some PROFILLER FS. If there is a blockage, remove the application tip and apply a small amount of PROFILLER FS directly from the syringe. Clean any debris from the mouth of the syringe, if present. Reinsert the application tip and reapply flowable composite. PROFILLER FS can also be applied by squeezing it onto an application pad and using a suitable tool.

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Fill the area to be filled step by step (2mm layering) using a suitable placement tool. Mixing the filler material with the syringe tip during insertion or gently scrubbing with a disposable brush post insertion helps eliminate possible bubbles and increases its flow into deeper pits and cracks.

Recap the syringe immediately after squeezing.

i. curing

You can apply the cure for approximately 20 seconds by shining a light on the product in the applied 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.)

Model	Curing Thickness	Light Application Time
A1,A2,A3,B1,White,Green,Blue,Orange,Yellow,Pink	2,0 mm	20 seconds
Black, Brown, Red,	2,0 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.

j. 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

If the patient is known to be allergic to any of the ingredients: application of the above materials is not appropriate. It is contraindicated in patients who are allergic to or hypersensitive to methacrylic and related monomers. 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.
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- Do not apply PROFILLER FS together with other resin composites or shades to prevent incomplete curing or entrapment of bubbles.
- Do not use PROFILLER FS for any purpose other than the purposes stated in the instructions for 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 FS causes an allergic reaction, a 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 FS.
- Avoid contact of the product with eyes, mucosal membranes, skin and clothes as it may cause an allergen reaction .
- PROFILLER FS should not be swallowed or inhaled.
- Check the condition of any syringe flow before applying it to the oral cavity. If you feel resistance, replace the tip and check again.
- 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 FS is supplied as a syringe. Products that are opened and left open may damage the material and design characteristics.
- PROMIDA DIŞ 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 PROFILLER FS 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 FS Fissure Sealant at a temperature between 2-27°C. Shelf life at the specified temperatures is 36 months (3 years) from the

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


date of production. AVOID direct light and heat contact.

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 number		Manufacturing Date
	Catalog Number		Manufacturer
	Use on time		Keep away from sunlight
	Warning, Consult the accompanying documents.		Refer to the Instructions for Use.
	Storage temperature range		Notified body
	Store in dry place.		

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