

READ CAREFULLY BEFORE USE

FIT SA

Light-cured Self-Adhesive Flowable Restorative

PRODUCT DESCRIPTION

FIT SA is a self-adhesive, light-cured, flowable restorative with two discrete viscosities, F03 (low flow) and F10 (high flow)

INDICATIONS FOR USE

- Class III and Class V restorations
- Small Class I restoration
- Base / Liner

PRECAUTIONS AND WARNINGS

1. Do not use this product on patients with known allergies to this material and/or methacrylate monomer.
2. Operators with known allergies to this material and/or methacrylate monomer must not use this product.
2. In case of any inflammation or other allergic reactions, immediately discontinue use and seek medical advice.
3. Use medical (dental) gloves and protective glasses to avoid sensitization to this product. In case of accidental contact with oral soft tissue or skin, immediately blot with alcohol moistened cotton ball, and rinse with plenty of water. Medical (dental) gloves provide some protection against direct contact with this material; however some monomers can penetrate through the gloves to reach the skin. Therefore, should this material contact the gloves, immediately remove them and wash hands with plenty of water.
4. In case of contact with eyes, immediately flush the eyes with plenty of water and seek medical advice.
5. Do not re-use needle tips.
6. Follow the instructions for use of each material, instrument or equipment to be used in conjunction with this product.
7. Do not use this product for any purposes other than specifically outlined in these instructions for use.
8. Use this product within the expiration date indicated on the package or container.
(Example YYYY-MM-DD → Year-Month-Date of the expiration date)

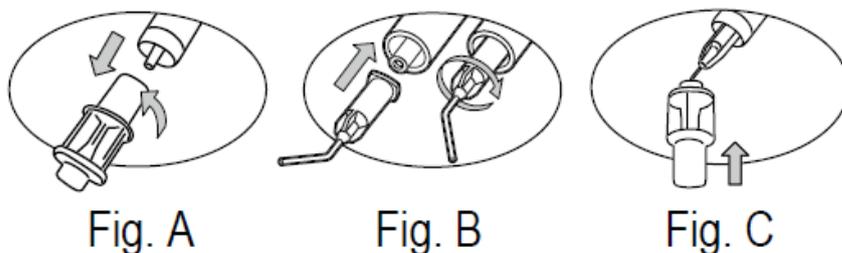
9. This product is intended for use by dental professionals only.

DIRECTIONS FOR USE

1. Preparation

When storing this material in a refrigerator, allow them to reach room temperature before use. Attach the needle tip to the syringe as indicated in the figures below.

- 1-1. Pull off the shield cap from the syringe while turning it slowly. (Fig. A)
 - 1-2. Attach the needle tip by turning it clockwise until it is securely attached. (Fig. B)
 - 1-3. Insert the needle tip into the small hole on the head of the shield cap immediately before use to protect the material from ambient light. (Fig. C)
- When replacing the needle tip, always use clean medical (dental) gloves.



2. Proper placement of the material

2-1. Cleaning of tooth surface

Thoroughly clean the tooth surface to remove plaque.

2-2. Shade selection

Select appropriate shade using a shade guide while the tooth is still moist.

2-3. Cavity preparation

Prepare the cavity following the standard method.

After cleaning with water spray, dry with air to remove excess moisture. Do not desiccate cavity surface.

2-4. Isolation

Isolate the restoration area with rubber dam.

2-5. Pulp protection

In case of iatrogenic pulp exposure or where the affected area is close to the pulp, cap with calcium hydroxide etc.

- Do not use eugenol containing materials since they might inhibit polymerization or adhesion of the material.

2-6. Application in thin layer

Dispense FIT SA into the prepared cavity and spread uniformly onto the cavity walls and floor (film thickness < 0.5 mm) with needle tip, hand instrument, or gently air blow as desired. Leave it undisturbed for 20 seconds and remove excess material.

- Phosphoric acid etching must not be performed on the dentin surface.

2-7. Light-curing

Light-cure with a dental light-curing unit. In cases where the restored area is large, light-cure in segments.

Light-curing unit	Halogen	LED
Light-curing time	10 sec.	5 sec.
Wavelength	400-500 nm	440-490 nm
Light intensity	$\geq 500 \text{ mW/cm}^2$	$\geq 1000 \text{ mW/cm}^2$

- Operators must use protective glasses or light shielding plate to avoid direct exposure to curing light. Operators must also protect patients' eyes from direct exposure to curing light.
- Disinfect the light-curing unit with alcohol after each use to avoid cross-contamination.

2-8. Filling

In case of Class III, V or small Class I cavity restoration, apply the material in increments of 2mm or less and light-cure each layer.

When applied as base/liner in deep cavity, after lining the cavity walls with FIT SA, build up restoration with universal or flowable composite resin in 2mm increments.

- Light-cure with a dental light-curing unit for each incremental filling.

Light-curing unit	Halogen	LED
Light-curing time	20 sec.	10 sec.

Use a dental light-curing unit having specifications equivalent to those described above.

- When layering the FIT SA for Class I, III and V restorations, light-cure each incremental layer immediately after application.
- The paste dispensed onto the paper pad should be shielded from ambient light with light-shielding cover to avoid premature polymerization.
- Discard the used needle tip after use and replace the shield cap securely. Needle tips should be used for only one patient and then discarded at the end of the procedure to avoid cross contamination. Do not re-use.
- Disinfect the syringe and shield cap with alcohol after each use to avoid cross-contamination. Then, close the cap securely. Use caution to avoid including alcohol into the paste.

2-9. Finishing and polishing

After light-curing, contour, finish and polish the restoration with following the standard method.

COMPOSITION

E3

UDMA, HEMA, Phosphonic acid monomer, S-PRG filler based on fluoroboroaluminosilicate glass,
Polymerization initiator, Pigments and others

SHADES

F03: A1, A2, A3, A4, B1

F10: A1, A2, A3, A4, B1

STORAGE

Store at refrigerator (1-10°C/34-50°F). Avoid high temperatures and high humidity. Keep away from direct sunlight and any source of ignition.

CAUTION: US Federal law restricts this device to sale by or on the order of a dental professional.

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