

Prior to use, carefully read the instructions for use. **EN**

## SOLARE Fio

LIGHT-CURED RADIOPAQUE FLOWABLE COMPOSITE

For use only by a dental professional in the recommended indications.

### INDICATIONS FOR USE

1. Liner or base
2. Blocking out undercuts
3. Repair of (in) direct aesthetic restorations, temporary crown & bridge, defect margins when margins are in enamel
4. Sealing hypersensitive areas
5. Fissure sealant
6. Direct restorative for II, III, IV, I and V cavities including small cavities which require high flowability

### CONTRAINDICATIONS

Avoid use of this product in patients with known allergies to methacrylate monomer or methacrylate polymer.

### Operation

1. Preparations
  - 1) Hold the syringe upright and remove the cap by turning counterclockwise.
  - 2) Promptly and securely attach the dispensing tip to the syringe by turning clockwise.
  - 3) Place the light protective cover until use.

#### Note:

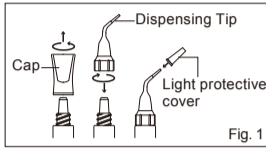
Take care not to attach the dispensing tip too tightly. This may damage its screw. In order to ensure a tight connection make sure that the threads are free of remnant material.

### 2. Shade Selection

Clean the tooth with pumice and water. Shade selection should be made prior to isolation.

Select the appropriate shade from shades of A1, A2, A3, A3.5. Shades are based on the Vita® classical shade guide.

\*Vita® is a registered trademark of Vita Zahnfabrik, Bad Säckingen, Germany.



### 3. Cavity Preparation

Prepare cavity using standard techniques. Dry by gently blowing with oil free air. Rubber dam is recommended to isolate prepared tooth from contamination with saliva, blood or sulcus fluid.

#### Note:

For pulp capping, use calcium hydroxide.

### 4. Bonding treatment

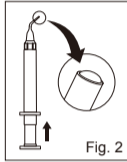
For bonding SOLARE Fio to enamel and/or dentine, use a light-cured bonding system such as SOLARE UNIVERSAL BOND, G-Premio BOND, G-BOND. Follow manufacturer's instructions.

### 5. Placement of SOLARE Fio

- 1) Remove cover from the dispensing tip.

#### Note:

1. Dispensing tip is securely attached to the syringe.
  2. Any possible air from the dispensing tip is removed by gently pushing forward the syringe plunger with the tip pointing upwards until material reaches the opening of the tip (Fig. 2).
- 2) Place the dispensing tip as close as possible to the prepared cavity, and slowly push the plunger to syringe material. Alternatively, dispense material onto a mixing pad and transfer to the cavity using a suitable instrument.



#### Note:

- a. If plugged, remove the dispensing tip and extrude a small amount of material directly from the syringe.
- b. Minimize exposure to ambient light. Ambient light can shorten the manipulation time.
- c. After use, immediately remove and dispose the dispensing tip and tightly close the syringe with the cap.

### Clinical Hint

In order to inject effectively, use the surface tension of the material to ensure uniformity across the entire surface of the restoration during build up. Once the required amount has been injected, release the pressure on the plunger and withdraw the syringe in a direction perpendicular to the surface. This will allow the material to separate from the dispensing tip and provides a smooth surface over the restoration.

### 6. Light Curing

Light cure the SOLARE Fio using a light curing unit. Keep light guide as close as possible to the surface. Refer to the following chart for Irradiation Time and Effective Depth of Cure.

Shade	Irradiation time	5 sec. (Plasma arc) (2000mW/cm <sup>2</sup> )
		10 sec. (High power LED) (more than 1200 mW/cm <sup>2</sup> )
		20 sec. (Halogen/LED) (700 mW/cm <sup>2</sup> )
A1, A2, A3		2.0mm
A3.5		1.5mm

#### Note :

1. Material should be placed and light cured in layers. For maximum layer thickness, please consult above table.
2. Lower light intensity may cause insufficient curing or discoloration of the material.

### 7. Finishing and Polishing

Finish and polish using standard techniques.

### SHADES

A1, A2, A3, A3.5

### STORAGE

Recommended for optimal performance, store in a cool and dark place (4-25°C / 39.2-77.0°F) away from high temperatures or direct sunlight.

### PACKAGES

1. Syringe 1 g (0.56 mL), 3 dispensing tip (plastic type), 1 light protective cover
- Dispensing tip package:
2. 30 dispensing tips (plastic type), 2 light protective covers
3. 30 dispensing tips (needle type), 2 light protective covers

### CAUTION

1. In case of contact with oral tissue or skin, remove immediately with cotton or a sponge soaked in alcohol. Flush with water. To avoid contact, a rubber dam and / or cocoa butter can be used to isolate the operation field from the skin or oral tissue.
2. In case of contact with eyes, flush immediately with water and seek medical attention.
3. Take care to avoid ingestion of the material.
4. Do not mix with other similar products.
5. Dispensing tips are for single use only. To prevent cross contamination between patients, do not reuse the dispensing tip. The dispensing tip cannot be sterilized in an autoclave or chemically.
6. Wear plastic or rubber gloves during operation to avoid direct contact with air inhibited resin layers in order to prevent possible sensitivity.
7. Wear protective eye glasses during light curing.
8. When polishing the polymerized material, use a dust collector and wear a dust mask to avoid inhalation of cutting dust.
9. Avoid getting material on clothing.
10. In case of contact with unintended areas of tooth or prosthetic appliances, remove with instrument, sponge or cotton pellet before light curing.
11. Do not use SOLARE Fio in combination with eugenol containing materials as eugenol may hinder SOLARE Fio from setting.
12. Do not wipe the dispensing tip with excessive alcohol as this may cause contamination of the paste.
13. Dispose of all wastes according to local regulations.
14. In rare cases the product may cause sensitivity in some people. If any such reactions are experienced, discontinue the use of the product and refer to a physician.
15. Personal protective equipment (PPE) such as gloves, face masks and safety eyewear should always be worn.

Some products referenced in the present IFU may be classified as hazardous according to GHS. Always familiarize yourself with the safety data sheets available at:

<http://www.gceurope.com>  
<http://www.gcamerica.com>  
<http://www.gcasidental.com>  
<http://www.gcindidental.com>

They can also be obtained from your supplier.

### CLEANING AND DISINFECTING:

MULTI-USE DELIVERY SYSTEMS: to avoid cross-contamination between patients this device requires mid-level disinfection. Immediately after use inspect device and label for deterioration. Discard device if damaged. DO NOT IMMERSSE. Thoroughly clean device to prevent drying and accumulation of contaminants. Disinfect with a mid-level registered healthcare-grade infection control product according to regional/national guidelines.

### Undesired effects- Reporting:

If you become aware of any kind of undesired effect, reaction or similar events experienced by use of this product, including those not listed in this instruction for use, please report them directly through the relevant vigilance system, by selecting the proper authority of your country accessible through the following link:

[https://ec.europa.eu/growth/sectors/medical-devices/contacts\\_en](https://ec.europa.eu/growth/sectors/medical-devices/contacts_en)  
 as well as to our internal vigilance system: [vigilance@gc.dental](mailto:vigilance@gc.dental)  
 In this way you will contribute to improve the safety of this product.

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Rx Only

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MANUFACTURED by  
**GC DENTAL PRODUCTS CORP.**  
 2-285 Torimatsu-cho, Kasugai, Aichi 486-0844, Japan

DISTRIBUTED by  
**GC CORPORATION**  
 76-1 Hasunuma-cho, Habashi-ku, Tokyo 174-8585, Japan

**EU: GC EUROPE N.V.**  
 Researchpark Hasselode-Leuven 1240, Interleuvenlaan 33,  
 B-3001 Leuven, Belgium TEL: +32 16 74 10 00

**GC AMERICA INC.**  
 3737 West 127th Street, Alsip, IL 60803 U.S.A.  
 TEL: +1-708-597-0900  
[www.gcamerica.com](http://www.gcamerica.com)

**GC SOUTH AMERICA**  
 Rua Heliodora, 399, Santana - 02022-051 São Paulo, SP - Brasil  
 Tel: +55-11-2925.0965  
 CNPJ: 08.279.999/0001-61  
 Responsável Técnica Mayara de Santos Ribeiro CRO/SP: 105.982

**GC ASIA DENTAL PTE. LTD.**  
 5 Tampines Central 1, #06-01 Tampines Plaza, Singapore 529541  
 TEL: +65 6546 7588

**GC AUSTRALASIA DENTAL PTY. LTD.**  
 1753 Botany Rd, Banksmeadow, NSW 2019, Australia  
 TEL: +61 2 9301 8200

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