

EQUIA Forte® HT Fil

BULK FILL GLASS HYBRID RESTORATIVE SYSTEM

Prior to use, carefully read the instructions for use.

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EQUIA Forte® Coat

LIGHT CURED SELF ADHESIVE WEAR RESISTANT COATING

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

INDICATIONS FOR USE

1. Class I restorations
2. Stress bearing Class II restorations (see separate technique guide for suggested cavity preparations)
3. Non-stress bearing Class II restorations
4. Intermediate restorative
5. Class V and root surface restorations
6. Core build up

EQUIA Forte Coat is used to seal, strengthen and protect the EQUIA Forte HT Fil restorations.

CONTRAINDICATIONS

1. Direct Pulp capping.
2. Avoid use of this product in patients with known allergies to glass ionomer cement, acrylate monomer, methacrylate monomer or methacrylate polymer.

NOT TO BE USED

EQUIA Forte Coat should not be used in combination with desensitizers and eugenol containing materials as these may hinder EQUIA Forte Coat from setting or bonding properly.

DIRECTIONS FOR USE

Powder/Liquid Ratio (g/g)	0.40/0.13
Mixing Time (sec.)	10"
Time of initial extrusion after mixing	10" maximum
Working Time (23°C/73°F) (min., sec.)	1'30"
Net Setting Time (37°C/99°F) (min., sec.)	2'30"
Finishing Time (37°C/99°F, from start of mixing) (min., sec.)	2'30"
Light curing time of EQUIA Forte Coat	20"

1. CAVITY PREPARATION

- a) Prepare tooth using standard techniques. Extensive mechanical retention is unnecessary. For direct pulp capping use calcium hydroxide.

In class V or II situations, we advise the use of an anatomical matrix system. Metal bands should be lubricated with a thin layer of petroleum jelly.

Note:

Optionally, CAVITY CONDITIONER or DENTIN CONDITIONER can be applied to the bonding surfaces.

- b) Rinse thoroughly with water. Blot away excess water with a cotton pellet or dry by gently blowing with an air syringe. DO NOT DESICCATE.

Prepared surfaces should appear moist (glistening).

2. CAPSULE ACTIVATION AND MIXING

- a) Before activation, shake the capsule or tap its side on a hard surface to loosen the powder.
- b) To activate the capsule, push the plunger until it is fully depressed with the main body and hold it down for 2 seconds.

Note:

1) Ensure the plunger is fully pressed to avoid the incorrect mixing ratio of powder and liquid.

2) The capsule should be activated just before mixing and used immediately.

3) Immediately set it into a mixer (or an amalgamator) and mix for 10 seconds (approximately 4,000 RPM).

3. RESTORATIVE TECHNIQUE

- a) Immediately remove the mixed capsule from the mixer and load it into the GC CAPSULE APPLIER.
- b) Make two clicks to prime the capsule then dispense. The working time is 1 minute 30 seconds from start of mixing at 23°C (73°F).

Higher temperatures will shorten working time.
- c) Within 10 seconds maximum after mixing, start to extrude the mixture directly into the preparation.
- d) Form the preliminary contour, and cover with a matrix if required.
- e) During the first 2 minutes 30 seconds from start of mix extra care should be taken to avoid moisture contamination or drying-out. In case this cannot be guaranteed, immediately apply EQUIA Forte Coat and light cure.

Note:

1) To adjust the direction of the nozzle, hold the applier with the capsule towards you and turn the capsule body.

2) To remove the used capsule, push the applier release button.

Twist the capsule and pull upwards.

4. FINISHING

Finish under water spray using superfine diamond burs after 2 minutes 30 seconds from start of mixing.

Note:

When applying EQUIA Forte Coat on the existing EQUIA Forte HT Fil restorations, roughen the surface to be coated with superfine diamond burs.

5. COATING

- a) Spray preparation dust away with water. Dry by gently blowing with oil free air. Surfaces to be coated should be dry. Do not desiccate.
- b) Bottle type:

Prior to dispensing, shake the bottle of EQUIA Forte COAT thoroughly. To open the flip-top cap, pinch both cap release buttons on the neck of the bottle at the same time, as illustrated in Figure 1. Dispense a few drops into a clean dispensing dish. Close the cap immediately. Note: 1) If the cap detaches from the bottle, it should be reattached by reseating the cap HORIZONTALLY on the plastic hinge pegs, and firmly pushing it back into place. The metal spring should be INSIDE the cap, as shown in Figure 2.
- 2) Wipe any excess liquid from the nozzle before closing the cap.
- c) Unitdose type:

Before opening unit dose capsule, ensure top of the capsule is facing up. Unscrew cap counterclockwise.

Note:

If the cap of the unit dose is too tight to open, use another unit dose. Do not try to open the unit dose capsule with excessive force as this may cause the liquid inside to spill and cause accidental contact with skin and eyes.

- c) IMMEDIATELY apply (within 1 minute after dispensing) to the surfaces to be coated using the disposable applicator. Use floss to apply to approximal surface. Avoid the content to soft tissue. DO NOT AIR BLOW.

Note:

1) Non bur cut enamel should be treated with a 35-40% phosphoric acid according to the manufacturer's instructions. Rinse and dry with oil free air.

2) Should the coated surface be contaminated with water, blood or saliva prior to light curing,

wash and dry the surface and repeat the coating procedure.

3) Ambient light may shorten the working time.

It is recommended to diminish the intensity or turn off your operation light during the cementation procedure.

4) If the cap of the unit dose is too tight to open, do not try to open it with force to avoid accidental contact of the liquid with skin and eyes. Use another unit dose.

5) Unit dose is disposable. Do not recap or reuse to avoid cross contamination between patients.

6. LIGHT CURING

IMMEDIATELY light cure all coated surfaces with a visible light curing unit (> 500 mW/cm² : Halogen, LED) for 20 seconds.

Note:

- 1) Place light source as close as possible to the coated surface.
- 2) If surface is tacky or yellowish, repeat light curing.
- 3) Use a protective light shield or similar protective eye wear during light curing.
- 4) EQUIA Forte Coat may produce a brief exothermic reaction.

Apply only a thin layer of EQUIA Forte Coat to avoid the excessive amount of exothermic reaction, otherwise it may cause damage to pulp.

STORAGE

Recommended for optimal performance, store EQUIA Forte Coat and EQUIA Forte HT Fil capsules (in the original aluminium foil) in a cool and dark place (4-25°C) (39.2-77.0°F).

SHADES

A1, A2, A3, A3.5, B1, B2, B3, C4

Shade numbers according to Vita® shade guide

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

PACKAGES

EQUIA Forte HT Fil

1. Single shade package: 50 capsules

2. Assortment package: 50 capsules (10 each of A2, A3, A3.5, B1, B3)

Average contents per capsule: 0.40 g powder and 0.13 g (0.10 mL) liquid

Minimum net volume of mixed cement per capsule: 0.14 mL

EQUIA Forte Coat

3. Bottle 4 mL (1)

4. Unit dose (0.1 mL) (50), Disposable Applicator (50)

Option: GC CAPSULE APPLIER (1 piece)

CAUTION

1. Personal protective equipment (PPE) such as gloves, face masks and safety eyewear should always be worn.
 2. In case of contact with oral tissue or skin, immediately remove with a sponge or cotton pellet. After the restorative treatment is finished, rinse thoroughly with water.
 3. In case of contact with eyes, flush immediately with water and seek medical attention.
 4. EQUIA Forte Coat is a highly flammable liquid and vapour. Do not use near open flame. Keep away from sources of ignition. Do not store large quantities in one area. Keep away from direct sunlight.
 5. EQUIA Forte Coat is volatile. Use in a well ventilated place. Replace cap immediately.
 6. If the tissue contacted by EQUIA Forte Coat turns white or forms a blister, advise the patient to leave the affected area undisturbed, until the mark disappears, usually in 1-2 weeks. To avoid contact, it is recommended to apply COCOA BUTTER to the area where rubber dam cannot cover.
 7. Avoid inhalation or ingestion of material.
 8. Avoid getting material on clothing.
 9. Do not mix with other products.
 10. Instruct the patient not to apply pressure for 1 hour.
 11. Use EQUIA Forte HT Fil with EQUIA Forte Coat.
 12. Dispose of contents / container in accordance with local regulations.
 13. 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.
- 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.gcasiadental.com>
They can also be obtained from your supplier.

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
as well as to our internal vigilance system: vigilance@gc.dental
In this way you will contribute to improve the safety of this product.

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