

BRILLIANT Bulk Fill Flow

Instructions for use

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Please read the Instructions for Use carefully before using the product.

PRODUCT DESCRIPTION

BRILLIANT Bulk Fill Flow is a flowable, radio-opaque, light-curing dental composite used for permanent filling therapy.

INTENDED USE / CLINICAL BENEFIT

- direct fillings of all cavity classes
- cavity lining
- fissure sealing
- blocking out of undercuts
- shape corrections to improve aesthetics
- repairs of ceramic and composite restorations
- adhesive luting of restorations if light penetration is possible
- luting of retainers

COMPOSITION BRILLIANT Bulk Fill Flow

Methacrylates
Dental glass
Amorphous silica

INDICATION

- tooth structure defects

CONTRAINDICATIONS

If any allergies exist to any components within BRILLIANT Bulk Fill Flow. If the application field cannot be isolated during application and curing of BRILLIANT Bulk Fill Flow.

SAFETY INSTRUCTIONS

⚠ WARNING

- The use of this product in the patient's mouth may only be undertaken by specialist personnel such as dentists and dental assistants with special qualifications.

NOTICE

- Keep out of the reach of children!
- Do not use the product beyond its expiry date.
- For hygienic reasons, the application needles are only intended for single use.
- BRILLIANT Bulk Fill Flow is light sensitive and should not be left too long under intensive light before curing, especially operatory light or sun light.
- Close syringes after use.
- Always wear gloves.
- For repairs, the treated surface must be roughened first.
- To avoid continued flow, pull back the plunger.
- In case of direct contact with the oral mucosa, rinsing with tap water is sufficient. In the case of contact with the eyes, rinse thoroughly with water (10 min) and consult an ophthalmologist showing these instructions for use.
- Contains nano materials (bonded particles)

SIDE EFFECTS / INTERACTIONS

No systemic side effects are known. Contact allergies with products of similar composition have been reported in isolated cases. Agents containing eugenol and / or oil of cloves may affect the polymerization of BRILLIANT Bulk Fill Flow. The use of zinc-oxide-eugenol cements in combination with BRILLIANT Bulk Fill Flow should therefore be avoided. Discolourations may occur when using cationic mouth rinses as well as plaque indicators or chlorhexidin.

USER- / PATIENT GROUP

Application through specialist dental personnel. Suitable for all patient groups.

PREPARATION

Cleansing the tooth

Cleanse tooth to be treated and the adjacent teeth using a brush and prophylaxis paste which does not contain fluoride.

Isolation of the cavity (dental dam)

Adequate isolation is absolutely necessary for achieving optimum results. The use of dental dams (e.g. from COLTENE) are recommended.

Matrix and inter-dental wedges

When working approximally, apply a thin matrix band. Fix the matrix proximally using interdental wedges.

Adhesive system

Apply adhesive system (e.g. from COLTENE) according to the corresponding instructions for use.

Preparation of the cavity

When preparing the cavity, every effort possible should be made to use a technique that preserves tooth structure (principle of the Adhesive Restoration Technique). Beveled enamel margins are recommended to increase the area of adhesion between tooth and filling material and thereby optimize the marginal seal.

Pulp Protection

Apply appropriate pulp protection in regions close to the pulp. Procedure according to manufacturer's instructions for use.

PROPER USE

a) Application of BRILLIANT Bulk Fill Flow for direct restorations

Application of BRILLIANT Bulk Fill Flow

Apply the material using the mounted application needle directly into the cavity.

Top layer

There is no need for a top layer. If required for aesthetic reasons, a top layer with universal composite (e.g. BRILLIANT EverGlow from COLTENE) can be applied.

b) Application of BRILLIANT Bulk Fill Flow for indirect restorations

Conditioning the inner surfaces/contact surfaces of the restoration

Always condition the contact surfaces of the restoration according to the manufacturer's instructions for use.

Application of BRILLIANT Bulk Fill Flow

Dispense the material using the mounted application needle directly into the restoration or cavity preparation. Position restoration in place using gentle pressure.

Removal of excess material

Remove coarse excess material (e.g. brush or spatula). Afterwards, hold restoration with pressure in position and remove additional excess material with a spatula or a suitable instrument.

Polymerisation

Cure BRILLIANT Bulk Fill Flow intra-orally with the blue light of any light curing unit (450-490 nm).

Maximum layer thickness: 4 mm

BRILLIANT Bulk Fill Flow must be cured layer by layer. The inhibition layer may not be removed for bonding between the increments. Insufficient exposure bears the risk of incomplete polymerisation. For safety concerns and to avoid overexposure the instructions for use of the curing light has to be respected.

Recommended curing time for direct restorations:

Cure for 20 s with at least 1000 mW/cm²

Recommended curing time for luting indirect restorations:

Cure each side for 40 s with at least 800 mW/cm²

Finishing

Use appropriate rotary instruments and polishers (e.g. from COLTENE) for shaping and polishing the occlusal and approximal surfaces. Fluoridate all surfaces after completion.

REPROCESSING, CLEANING, DISINFECTION AND MAINTENANCE

For the syringe, the use of a disposable sleeve is recommended. In case of suspected or identifiable contamination, dispose of the syringe as described below.

Disinfection in a washer-disinfector or steam sterilization in an autoclave is not possible.

SHELF LIFE / STORAGE

Expiry date and LOT number: see primary packaging

Storage temperature: 4 -23 °C / 39 - 73 °F

Shelf life after first opening: expiry according to the expiry date

Protect against exposure to heat and sun. Avoid extreme temperature fluctuations. Close syringes immediately after use.

DISPOSAL

Dispose of waste according to applicable legislation. Special country-specific regulations may apply. Can be disposed together with household waste in compliance with official regulations in contact with approved waste disposal companies and with authorities in charge. (Only dispose of completely emptied packages.)

TECHNICAL DATA

Complies with ISO 4049 Type 1, Class 2, Group 1

Range of dimensions of inorganic filler particles: 0.02 – 5.0 µm

Inorganic filler content by volume: 38.5 %

Inorganic filler content by weight: 56 %

REPORTING OBLIGATION

All serious incidents occurring in conjunction with this product must be reported immediately to the manufacturer as well as to the competent authority.


SAFETY DATA SHEET / SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

www.coltene.com


Glossary

 Consult instructions for use

 Keep away from sun light

 Single use only

 Temperature limitation

 Legal Manufacturer

 Expiry Date

 Batch Code

 RX only

 Medical Device

 Manufacturing Date

 Unique Device Identifier

 Reference Number

 Importer

Coltène/Whaledent AG

Feldwiesenstrasse 20
CH-9450 Altstätten/Switzerland
T +41 71 757 5300
F +41 71 757 5301
info.ch@coltene.com