

For prior use, carefully read the instructions for use. EN

everX Flow™

SHORT-FIBRE REINFORCED FLOWABLE COMPOSITE FOR DENTIN REPLACEMENT

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

INDICATIONS FOR USE

everX Flow is a dentin replacement material suitable for:

1. All direct composite restorations including large posterior cavities, all deep cavities and endo-treated teeth, cavities with missing cusps or root amalgam removal and cavities where inlays and onlays should not be recommended.
2. Core build-up

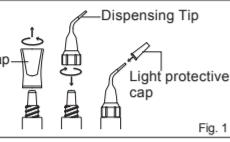
Although everX Flow features a high strength and fracture toughness, it should always be fully covered with a layer of light-cured universal restorative composite to ensure sufficient wear resistance.

CONTRAINdications

1. Direct composites
2. Avoid use of this product in patients with known allergies to methacrylate monomer or methacrylate polymer.
3. Not to be used as dentin and surface composite layer. Always cover with a layer of light-cured universal composite.

DIRECTIONS FOR USE

1. Preparations
 - a) Hold the syringe and remove the cap by turning counter-clockwise.
 - b) Safely attach the dispensing tip to the syringe by turning clockwise.
 - c) Place the light protective cap onto the tip.



Note:
Take care not to twist the dispensing tip too tightly. This may result in the screw. In order to ensure a light connection, make sure that there is no free of remnant material.

2. Shade Selection

Select shade with punch and water. Select the appropriate shade of everX Flow or Bulk shade or Dentin shade. Refer to 6. Light-curing for the respective depth of each shade.

Note:
Shade selection of the final composite layer should be made prior to isolation.

3. Cavity Preparation

Wet the cavity using standard techniques. Dry by gently blowing with oil free air. The use of a rubber dam is recommended to isolate the prepared tooth from contamination with saliva, blood and tissue.

Note:
For pulp capping, use calcium hydroxide.

For bonding everX Flow to enamel and/or dentin, use a light-cured bonding system such as G-BOND (Fig. 1). Follow manufacturer's instructions.

4. Placement of everX Flow – see note for Class I and large cavities

a) Remove the light protective cap from the syringe.

Note:
Prior to isolating the material into the cavity, make sure to check the following:

- 1) The dispensing tip is securely attached to the syringe.

2) Any possible air from the dispensing tip is removed by gently pressing forward the syringe until the material reaches the opening of the tip (Fig. 3).

b) Place the dispensing tip as close as possible to the cavity floor and slowly push the plunger to extrude material (Fig. 4). When placing everX Flow in the cavity, verify that the dispensing tip is not overlapping composite on all surfaces of the restoration (refer 7. Placement of the composite). Note – Class II and large cavities

1) Use a suitable matrix system to establish the correct contact area.

2) When placing everX Flow in a Class II or a large cavity, build first the missing wall with a thin layer of light-cured restorative composite before placing everX Flow. The wall should be thick enough to withstand the application pressure of everX Flow.

Note:
1) If the dispensing tip is plugged, remove it and extrude a small amount of material directly from the syringe.

2) When curing, use a low intensity light.

Ambient light can shorten the manipulation time.

3) After use, immediately remove and dispose of 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 disperse uniformly across the entire surface of the restoration during build up. Once the required amount has been injected, release the pressure on the plunger and move the dispensing tip 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

Wear everX Flow using a light-curing unit. Keep the light guide close as possible to the surface (Fig. 6). Refer to the following chart for irradiation Time and Effective Depth of Cure.

Irradiation Time and Effective Depth of Cure

Irradiation time 10 sec. (High Power LED) (>1200 mW/cm²)

Bulk shade 5.5 mm

Dentin shade 2.0 mm

Note:
Only the Bulk shade can be placed using a bulk application. The Dentin shade should be placed and light-cured in layers as described in the above table.

The Dentin shade may cause insufficient curing or discoloration of the material.

7. Placement of the overlaying composite

Fill the remaining cavity space with a wear-resistant and polishable restorative composite as recommended by the manufacturer.

everX Flow should have a thickness of 1.2 mm on the occlusal surface.

8. Finishing and Polishing

Check and adjust the occlusion. Finish and polish using standard techniques.

SHADES

everX Flow is available in two shades: Bulk shade and Dentin shade.

STORAGE

Recommended for optimal performance, store in a cool and dark place (4-25°C / 39-77.0°F) away from high temperatures or direct sunlight.

9. 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 with a rubber diaphragm or COCOA BUTTER can be used to remove the material from the oral tissue.

Medical attention should be sought if the material enters the eye.

10. Do not mix with other similar products.

Dispensing tips are for single use only. To prevent cross-contamination between patients, do not reuse the dispensing tip.

Dispensing tips should be sterilized in an autoclave or chemicals.

Wear protective eye glasses during light curing.

Wear the protective material, use a dust collector and wear a dust mask to avoid inhalation of cutting dust.

Avoid getting material on clothing.

Keep the protective material out of areas of tooth or prosthetic appliances, remove with instrument, sponge or cotton ball before light curing.

everX Flow in combination with eugenol containing materials as eugenol may hinder everX Flow from setting.

Do not wipe the dispensing tip with excessive alcohol as this may damage the tip.

13. Dispose of all wastes according to local regulations.

In rare cases the product may cause sensitivity in some people. If sensitivity occurs, discontinue the use of the product and refer to a medical professional.

Personal protective equipment (PPE) such as gloves, face masks and safety eyewear should always be worn.

Some products are listed in the present IFU may be classified as hazardous according to GHS. Always familiarise yourself with the safety data sheets available at <http://www.geurope.com>.

They can also be obtained from your supplier.

CLEANING AND DISINFECTION

MULTI-USE DELIVERY SYSTEMS: To avoid cross-contamination between patients, use a mid-level disinfection.

Immediately after use, clean and dry device and let it dry for 24 hours.

Discard device if damaged.

Thoroughly clean device to prevent drying and accumulation of components. Disinfect with a mid-level registered healthcare-grade infection control product according to regional / national guidelines.

Undesired effects - Report:

If you become aware of any kind of undesired effect, reaction or side effects 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 at https://ec.europa.eu/growth/sectors/medical-devices/contacts_en, as well as to our internal vigilance system: vigilance@gc.dental. In this way we will contribute to improve the safety of this product.

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Dernière mise à jour: 01/2021

Letzte Aktualisierung: 01/2021

Algunos productos mencionados en el presente modo d'emploi peuvent être classifiés comme des substances sensibilisantes dans les fiches de données de sécurité disponibles sur <http://www.geurope.com>. Elles peuvent également être obtenues auprès de votre fournisseur.

NETTOYAGE ET DESINFECTION

SISTÈME DE DISTRIBUTION MULTIFONCTION: Pour éviter toute contamination croisée entre les patients, ce dispositif doit être stérilisé et nettoyé immédiatement après l'utilisation, conformément aux instructions de l'étiquette. Jeter le dispositif s'il est endommagé.

NE PAS IMMERGER. Pulir con cura el dispositivo para prevenir la polimerización excesiva del compuesto.

Possano anche essere richieste al fornitore.

Algunos productos citados en el presente modo d'emploi peuvent être classifiés comme des substances sensibilisantes dans les fiches de données de sécurité disponibles sur <http://www.geurope.com>. Elles peuvent également être obtenues auprès de votre fournisseur.

REINIGUNG UND DESINFektION

DISPACK-ZUM-MULTI-ANWENDEN-GEBRAUCH: um Kreuzinfektionen zwischen Patienten zu verhindern, ist eine Desinfektion mit einem geeigneten Desinfektionsmittel erforderlich.

Produkt direkt nach dem Gebrauch auf Abnutzung oder Beschädigung untergebracht und sollte sofort sterilisiert werden.

Niemals TAUCHEN/SINFIZIEREN. Das Material gründlich reinigen und vor Feuchtigkeit schützen, um Kreuzkontaminationen zu verhindern. Keine eugenolhaltigen Produkte verwenden, da diese zudem die Anwendung von everX Flow beeinträchtigen.

everX Flow ist außerdem bei Ihrem Zulieferer erhältlich.

REINIGUNG UND DESINFektION

VERPACKUNG ZUM MULIT-ANWENDEN-GEBRAUCH: um

Nebenwirkungen, Reaktionen oder ähnliche Vorkommnisse.

Nettoyez so rigoureusement que l'agent de désinfection ne puisse pas pénétrer dans les structures de l'appareil.

NON IMMERGER. Pulir con cura el dispositivo para prevenir la polimerización excesiva del compuesto.

Desinfectar con un producto de control de la infección de nivel intermedio según las directrices regionales / nacionales.

Déclaracion d'effets indésirables:

Si vous avez connaissance d'un effet indésirable, réaction ou autre effet de type résultant de l'utilisation de ce produit, indiquer que ce produit n'est pas recommandé dans cette notice, veuillez signaler directement via le système de vigilance approprié, en sélectionnant l'autorité compétente de votre pays ou de votre région: https://ec.europa.eu/growth/sectors/medical-devices/contacts_en

et pour l'Amérique: <http://www.gcamerica.com>

Où vous pouvez également être informé par votre fournisseur.

MELDUNG UND UNERWÜNSCHTER VORKOMMENISSE

Wenn Sie bei der Verwendung des Produkts unerwünschte Nebenwirkungen, Reaktionen oder ähnliche Vorkommnisse feststellen, so richten Sie sich bitte an die entsprechende Anwendungseinheit, obwohl es sich um eine aufgerollte Form handelt.

Die Anwendungseinheit kann über die entsprechende Anwendungseinheit, die Sie unter der Link

https://ec.europa.eu/growth/sectors/medical-devices/contacts_en finden, oder unter der Internen Meldestelle: vigilance@gc.dental

Auf diese Weise tragen Sie dazu bei, die Sicherheit dieses Produktes zu verbessern.

Dernière mise à jour: 01/2021

Letzte Aktualisierung: 01/2021

Algunos productos mencionados en las presentes instrucciones pueden clasificarse como perjudiciales según GHS. Siempre familiarícese con las hojas de datos de seguridad disponibles en <http://www.geurope.com> o en América: <http://www.gcamerica.com>

Ellos pueden igualmente ser obtenidos de su proveedor.

LIMPIEZA Y DESINFECCIÓN

SISTEMA DE UTILIZACIÓN MULTI-USOS: para evitar la contaminación cruzada entre los pacientes, este dispositivo requiere la desinfección de nivel medio. Inmediatamente después de su uso, informelos directamente a través del sistema de vigilancia correspondiente de su país. Acceso a través del siguiente enlace:

https://ec.europa.eu/growth/sectors/medical-devices/contacts_en

o para América: <http://www.gcamerica.com>

También puede obtener información sobre su proveedor.

R& Only

everX Flow es beneficiaria en tres tipos:

Kleur Bulk y kleur Dentin.

OPSLAG

Anvændning for et optimalt resultat, bewar på en kold og

drynede plads (4-25°C / 39.2-77.0°F) weg af høje temperaturer og direkte sollys.

Verdenskort med et omfangsrigt produktoversigt.

Verdenskort med

