Fluoride Releasing Bulk Fill Flowable Restorative Material

BEAUTIFIL-Bulk Flowable is a light-cured radiopaque flowable restorative material. It is predominantly designed to be used as a base in Class I and II restorations and can be placed in 4 mm increments. BEAUTIFIL-Bulk Flowable is overlayed with universal or posterior restorative material to replace missing occlusal/facial enamel.

SHADES
Universal(U), Dentin(D)

COMPOSITION
Bis-GMA, UDMA, Bis-MPEPP, TEGDMA, S-PRG filler based on fluoroboroaluminosilicate glass, Polymerization initiator, Pigments and others

INDICATIONS
1. Base in Class I and II direct restorations
2. Liner under direct restorative materials
3. Restorations of small posterior cavities (including occlusal restorations)

PRECAUTIONS
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.
3. Do not re-use tips.
4. If any inflammation or other allergic reactions occur on either patient or operator, immediately discontinue use and seek medical advice.
5. 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 very quickly to reach the skin. Therefore, should this material contact even the gloves, immediately remove them and wash hands with plenty of water.
6. In case of contact with eyes, immediately flush the eyes with plenty of water and seek medical advice.
7. This product is intended for use by dental professionals only.

DIRECTIONS FOR USE
1. Cleaning of tooth surface
Thoroughly clean the tooth surface to remove plaque.

2. Shade selection
Select the appropriate shade of universal or posterior restorative material using the respective shade guide while the tooth is still in moist

3. Cavity preparation
Prepare the cavity following the conventional method.

4. Isolation
Use a rubber dam etc to isolate the treatment area from contamination.

5. Placement of matrix
Place a matrix band in the case where the cavity involves proximal area. Follow the matrix manufacturer's instructions for use.

6. Pulp protection
In the case where the pulp is exposed or the affected area is close to the pulp, cap the pulp with calcium hydroxide etc.

7. Adhesive application
Apply dentin adhesive following the manufacturer's instructions for use.

8. Delivery
Insert a BEAUTIFIL·Bulk Flowable Tip into the dispenser.
  • When applying the material directly into the cavity, sterilize the dispenser before and after use.

9. Application
Dispense the material directly into the cavity from the bottom to at least 2 mm short of the occlusal cavosurface. In order to prevent the formation of air bubbles, gradually withdraw the tip as cavity is filled.
  • In deeper preparations, place material in 4 mm increments.
  • When storing these materials in a refrigerator, allow them to reach room temperature before use.
  • Tip should be used for only one patient and then discarded at the end of the procedure to avoid cross-contamination.

10. Light-curing
Light-cure each layer using a dental light-curing unit.

Light-curing time and depth of cure by each dental light-curing unit

<table>
<thead>
<tr>
<th>Shade</th>
<th>Depth of cure</th>
<th>Halogen light-curing unit</th>
<th>LED light-curing unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Universal</td>
<td>4 mm</td>
<td>20 sec.</td>
<td>10 sec.</td>
</tr>
<tr>
<td>Dentin</td>
<td>4 mm</td>
<td>40 sec.</td>
<td>20 sec.</td>
</tr>
</tbody>
</table>

*Halogen light-curing unit

Light source: Halogen, Wavelength: 400-500 nm, Light intensity: 500 mW/cm² or more

*LED light-curing unit

Light source: Blue LED (with a single emission peak), Wavelength: 440-490 nm, Light intensity: 1000 mW/cm² or more

• Use a dental light-curing unit having specifications equivalent to those described above. When
using the one having performance other than these recommendations, follow the instructions for use of each dental light-curing unit to light-cure BEAUTIFIL-Bulk Flowable properly.

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

11. Complete the restoration
Place universal or posterior restorative material directly over the cured BEAUTIFIL-Bulk Flowable. After light-curing, contour, finish and polish the restoration following the conventional method.

NOTE ON USE
1. Do not use eugenol containing materials since they might inhibit polymerization or adhesion of the material.
2. Follow the instructions for use of each dental material, equipment or instrument to be used in conjunction with this product.
3. Do not use this product for any purposes other than specifically outlined in the INDICATIONS in these instructions for use.
4. Use this product within the expiration date indicated on the package and container.
   (Example YYYY-XX→Shelf life: at the end of XX month, YYYY year)

STORAGE
Store in a dark place at room temperature (1-30 °C / 34-86 °F). Avoid high temperatures and high humidity. Keep away from direct sunlight and any source of ignition.