BEAUTIFIL-Bulk Restorative
Fluoride Releasing Bulk Fill Restorative Material

BEAUTIFIL-Bulk Restorative is a visible light-cured radiopaque restorative material. It is predominantly designed to be used for posterior restorations including occlusal surfaces and can be placed in 4 mm increments.

SHADES
Universal(U), A

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

INDICATIONS
Direct posterior 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 the patient or operator while using this product, 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. In case of contact with eyes, immediately flush the eyes with plenty of water and seek medical advice.
6. 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 appropriate shade using a shade guide while the tooth is still 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 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. Flowable application
   To achieve optimal adaptation of the prepared tooth, apply a flowable restorative material as a liner.

9. Application
   Dispense adequate amount of BEAUTIFIL-Bulk Restorative onto a paper pad from the syringe. Apply the dispensed material into the cavity using a suitable instrument and create the shape desired. When using a tip, insert the tip into the dispenser (BEAUTIFIL Tip Dispenser etc) to apply the material directly into the cavity. The tip material may also be dispensed onto a paper pad to be applied into the cavity with a suitable instrument. In deeper preparations, place material in 4 mm increments.

10. Light-curing
   Light-cure each layer (up to 4 mm increment) using a dental light-curing unit. In the case where restored area is large, divide it into some parts to light-cure.

<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, A</td>
<td>4 mm</td>
<td>20 sec.</td>
<td>10 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

11. Finishing and polishing
   After light-curing, contour, finish and polish following the conventional method.

**NOTE ON USE**

1. 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 of each unit to light-cure BEAUTIFIL-Bulk Restorative properly.
2. Operators must use protective glasses or light shielding plate etc to avoid looking directly at the
3. In the case where pulp is exposed or the affected area is close to the pulp, cap the pulp with calcium hydroxide etc.
4. Do not use eugenol containing materials since they might inhibit polymerization or adhesion of the material.
5. Tightly close the cap after each use.
6. The paste dispensed onto the paper pad should be shielded from ambient light by light-shielding cover to avoid unintended polymerization of the material.
7. The tip should be used for only one patient and then discarded at the end of the procedure to avoid cross contamination.
8. When applying the material directly into the cavity, sterilize the dispenser before and after use.
9. Follow the instructions for use of each dental material or instrument to be used in conjunction with this product (including BEAUTIFIL Tip Dispenser etc).
10. When storing these materials in a refrigerator, allow them to reach room temperature before use.
11. Do not use this product for any purposes other than specifically outlined in the INDICATIONS in these instructions for use.
12. Use this product within the expiration date indicated on the package and the 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.

**CAUTION: US Federal law restricts this device to sale by or on the order of a dental professional.**

Single use (Tip)