Statement on CERASMART™ by GC

June 24, 2015
GC CORPORATION

On June 12, 2015, 3M ESPE announced “A Change in Indication” by removing the crown indication for Lava™ Ultimate CAD/CAM Restorative blocks, because crowns are debonding at a higher-than-anticipated rate and, therefore, are not consistently meeting 3M’s standards for quality and performance. The product continues to be indicated for inlays, onlays (with an internal retentive design element) and veneer restoratives, per new Instructions for Use (IFU).

Under this circumstance, GC would like to inform you of our key message on the usage of CERASMART™ (GC) with these statements:

1. CERASMART™ (GC) performs well (complaint rate: < 0.0218%) after more than half million restorations.
   No change in indication - Inlays, Onlays, Crowns and Veneers
2. The impact factors on bonding are the following:
   a. Preparation design
   b. Cementation procedure

“DO THE RIGHT THING!”

- Sandblasting is recommended as a pre-treatment of CERASMART (GC). If sandblasting is not available, Hydrofluoric acid treatment is recommended.
- CERAMIC PRIMER II (GC) pre-treatment on CERASMART (GC) is the key step
- Recommended adhesive cement is a conventional adhesive resin cement

NOTE: Confirmed cementation procedure for CERASMART (GC) can be found on the 2nd page of this statement
CEMENTATION PROCEDURE:

1. With sandblasting treatment:
   - Sandblasting with 25-50µm alumina 0.15MPa/1.5bar is recommended
   - Blow the restoration with an oil-free air syringe or clean with an ultrasonic cleaner and dry
   - Clean with alcohol to remove oil residue
   - Treat the surface with a silane coupling agent such as CERAMIC PRIMER II (GC)
   - Cement with a conventional resin cement (luting composite) and bonding agent

NOTE: Prior to using CERAMIC PRIMER II (GC) or resin cement, refer to the respective manufacturer’s Instructions for Use of the manufacturer

2. Without sandblasting technique:
   - Treat with hydrofluoric acid (5%) for 60 seconds
   - Wash with water spray or an ultrasonic cleaner and dry
   - Clean with alcohol to remove oil residue
   - Treat the surface with a silane coupling agent such as CERAMIC PRIMER II (GC)
   - Cement with a conventional resin cement and bonding agent

ADDITIONAL APPLICATION AND REPAIR:
- Roughen the bonding area using a diamond point or carbide bur
- Apply CERAMIC PRIMER II (GC) to improve adhesion and dry the surface
- Apply the chosen composite restorative material as required
- G-aenial™ Universal Flo (GC) is recommended to make the surface of the restoration homogeneous, as it consists of the same flexible nano ceramic technology as CERASMART™

Alternatively, OPTIGLAZE™ Color (GC) is also recommended for surface characterization and glazing technique:
- Sandblast with 25-50µm alumina (0.15MPa/1.5bar.), clean and dry
- Apply CERAMIC PRIMER II (GC), dry
- Apply OPTIGLAZE™ Color (GC)
  - OPTIGLAZE™ Color (GC) can only be cured with a light-curing device with a wavelength of 400-430nm – refer to the respective instructions for use

NOTE:
1. Be sure to clean the restoration well after try-in
2. If milled by a laboratory, please follow the same protocol

For further information about GC products visit our website at www.gcamerica.com
or contact the GC Customer Service center 800-323-7063