

Notice: Change in Indication — Lava™ Ultimate Restorative

Effective June 12, 2015. 3M Oral Care is removing the crown indication for Lava™ Ultimate CAD/CAM Restorative product because crowns are debonding at a higher-than-anticipated rate and therefore not consistently meeting 3M's high 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).

We have informed the FDA and letters have been mailed to our customers in dental offices and labs (milling centers) that have purchased Lava Ultimate materials. Customer letters include the new IFUs, acknowledgment form and process for return of unneeded product.

There is no need to contact patients with existing Lava Ultimate restorations or to take additional action beyond normal patient care. This is not a safety issue, as health risks associated with crown debonding have been determined to be low in severity and occurrence.

We apologize for any inconvenience this may have caused. As a pioneer in dental materials, we have high standards of performance. We'll continue to leverage 3M science to provide innovative dental products.

If you have questions, please contact
3M Oral Care Customer Care: 1-800-634-2249.

CLICK TO DOWNLOAD:

Lava™ Ultimate CAD/CAM Restorative
Instructions for Use (198KB)



Lava™ Ultimate CAD/CAM Restorative
for Lava™ Mill Instructions for Use (188KB)

