

3M ESPE Dental

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June 19, 2015

Return Receipt Requested

MEDICAL DEVICE CORRECTION**3M™ ESPE™ Lava™ Ultimate CAD/CAM Restorative****3M™ ESPE™ Lava™ Ultimate Implant Crown Restorative****Attention:** Dentists and Other Dental Professionals**Affected Product/Lot:** 3M ESPE Lava Ultimate CAD/CAM Restorative and **3M™ ESPE™ Lava™ Ultimate Implant Crown Restorative** – All Lots and Catalogue Numbers**Corrective Action:**

3M ESPE Dental is voluntarily removing the crown indication from the list of indications for use of Lava Ultimate materials.

Reason for Field Correction:

Approximately 10% of dental accounts have reported to 3M that Lava Ultimate crowns debonded at a rate higher than their typical experience for crowns. The reported debond rates varied greatly and often significantly exceeded the 2-4% rates generally reported in clinical literature. Based on this customer feedback, the product is not meeting performance expectations for consistent and predictable outcomes for the crown indication. 3M is taking this action consistent with its commitment to provide high quality products to dental professionals and their patients.

Potential Patient Impact:

Health risks associated with crown debonding have been determined to be low in severity and occurrence. There is no need to contact patients with existing Lava Ultimate restorations or to take additional action beyond normal patient care.

Continued Use for Inlay, Onlay and Veneer Indications:

Lava Ultimate materials are still indicated and can be used for inlays, onlays (with internal retentive elements) and veneer restorations. Clinical and customer feedback support continued use.

Action Required:

- We ask that you sign the enclosed acknowledgement form that we have informed you on the corrective actions and you have understood the changes
- Share this information with all members of your staff
- Discard all copies of previous IFUs. New IFUs will be provided shortly.

If you have questions, do contact our 3M ESPE Account Managers:

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Janice Lim (9731 6355)

Francis Tan (9690 8811)

We apologize for any inconvenience this may have caused and thank you for your attention to this matter.

Katherine Kum
Division Manager
3M ESPE Dental Division

Mabel Low
General Manager
3M Healthcare Business