



22 June 2015

URGENT: Field Safety Corrective Action

3M™ ESPE™ Lava™ Ultimate CAD/CAM Restorative

Dear Dental Products Distributor:

This letter is to bring to your attention that 3M ESPE is taking the following action with regards to Lava Ultimate materials:

- Removing the crown indication: We are voluntarily removing crowns from the list of indications because crowns are debonding at a higher-than-anticipated rate and therefore not meeting 3M's high standards for quality and performance.
- Clarifying the remaining indications: Lava Ultimate material is still indicated and can be used for inlays, onlays (with internal retentive elements) and veneer restorations in accordance with the enclosed updated Instructions for Use (IFU).

There is no elevated risk to patients. Risk is consistent with other crowns. However, the rate of debonding is higher than expected and therefore does not meet 3M's quality standards.

Action Required – Recall of Distributor Inventory for Labeling Revision:

- Do NOT ship Lava Ultimate restorative product(s) to customers.
- Contact Jaeson Duckworth your 3M ESPE Channel Manager (Mob: 07970 617532) to arrange for return.
- Share the information about change in indications and IFUs with your staff.
- 3M is asking that you please work with your 3M Key Account Manager to contact all dentists and lab/milling centers who have purchased Lava Ultimate products to provide the updated information and corrected IFUs. A copy of the letter is enclosed for your information.

We expect that Lava Ultimate products with updated labeling and instructions for use will be available in 4–6 weeks.

3M ESPE Dental

We apologise for any inconvenience this may cause, and thank you for your continued partnership and support.

If you have any questions in relation to this matter, please contact Jaeson Duckworth on the number given above.

Jonathan P Young

General Sales and Marketing Manager - 3M ESPE Division

Enclosure:

1. Customer Notification Letter
2. Updated IFU's for Lava Ultimate
3. Customer Field Correction Acknowledgement Form