HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

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

Priority 2 – Warning

HPRA Safety Notice: SN2015(22) **Issue Date: 13th August 2015**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
3M ESPE	V24561

ISSUE

3M have become aware following customer feedback that Lava Ultimate crowns have debonded at a rate significantly higher than the 2-4% rates generally reported in clinical literature for crowns.

3M ESPE has issued a Field Safety Notice to notify users that the crown indication has been removed from the list of indications for use of Lava Ultimate CAD/CAM Restorative. All lots and catalogue numbers of this product are impacted.

ACTION OR RECOMMENDATIONS

The HPRA advises that users/distributors:

1 Check your inventory to determine if you have the affected products.

2 Follow the instructions outlined in the Field Safety Notices (see user and distributor field safety notices attached) and complete the customer reply form provided by 3M ESPE.

3 Discard all copies of the previous Instructions For Use (IFU).

4 Forward a copy of this HPRA Safety Notice to all those who need to be aware of this issue within your organisation and to any organisation / person to whom these devices have been transferred.

TARGET GROUPS

Dentists / Dental Nurses
Dental Technicians
Dental Hygienists / Dental Auxiliaries
Dental Lab/Milling Centres
Dental Surgeons
Dental Product Distributors / Subsidiaries

BACKGROUND

3M ESPE has issued a Field Safety Notice to notify users that the crown indication has been removed from the list of indications for use of Lava Ultimate CAD/CAM Restorative. All lots and catalogue numbers of this product are impacted.

The IFU has been updated to inform users not to use Lava Ultimate restorative for any type of crown because there exists a potential for debonding. The updated IFU states that Lava Ultimate restorative is indicated for inlays, and onlays (with internal retentive design elements) and veneers.

MANUFACTURER / AUTHORISED REPRESENTATIVE/ DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

3M ESPE Dental Products, 2510 Conway Ave, building 260-2A-11, St.Paul, USA, MN 55144-1000

Telephone: +1 651 733 7698
Fax:
E-mail: mbevan1@mmm.com
Website: www.3m.com

Enquiries to the **authorised representative** should be addressed to:

3M Deutschland GmbH, Carl-Schurz-Stabe 1, Neuss, Germany, 41453

Telephone: +49 8152 700 1327
Fax: +49 8152 700 1869
E-mail: sbmed@mmm.com
Website: www.3m.com

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie