IRISH MEDICINES BOARD

Notice Information: - Recall
10 August 2011

Part 1. Product Information

a)	Title:	Dycal Radiopaque Calcium Hydroxide Composition Cavity Base/Liner
b)	Product Name/Type:	Dycal Radiopaque Calcium Hydroxide Composition Cavity Base/Liner
c)	Reference:	SN2011(19)
d)	Manufacturer/Supplier:	DENTSPLY Caulk, USA.

Part 2. Target Audience

a)	Target Audience:	Dental Practitioners Distributors

Part 3. Problem/Issue

a)	Problem/Issue:	DENTSPLY has become aware that certain lots of Dycal may exhibit faster setting times than is normal for these products

Part 4. Background Information

a)	Background Information:	DENTSPLY has confirmed that this issue is limited to specific lot numbers (see attached field safety notice, FSN). DENTSPLY has published a FSN and has undertaken a recall of the affected product lots.

Part 5. Action to be taken

a)	Action to be taken:	DENTSPLY has been unsuccessful in their attempts to locate all devices affected by this field safety corrective action (FSCA), as one of the distributors in Ireland, O'Neill Dental Ltd., has ceased trading and there are no customer records available to assist traceability. The IMB advises that users: • Identify the affected devices in your facility. • If you have affected devices, follow the manufacturer's recommendations as outlined in the attached FSN and contact DENTSPLY to arrange for return

Part 6. Enquiries

a)	All enquiries should be made to:	Enquiries to the European authorised representative should be addressed to: Mr. Torsten Riedel Divisional Complaint Officer / Quality Assurance DENTSPLY DeTrey GmbH De-Trey-Straße 1 78467 Konstanz Germany Telephone: +49 75 31 / 5 83 2 61 Fax: +49 75 31 / 5 83 660 710 E-mail: torsten.riedel@dentsply.com All adverse incidents relating to a medical device should be reported to the: Irish Medicines Board Kevin O'Malley House Earlsfort Centre Earlsfort Terrace Dublin 2 Telephone: +353-1-6764971 Fax: +353-1-6344033 E-mail: vigilance@imb.ie Website: www.imb.ie Please click here to download PDF version of Safety Notic

Website: www.imb.ie

Please click here to download PDF version of Safety Notice

Please click here to download PDF version of the field safety notice