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NOTICE**

# Dycal Radiopaque Calcium Hydroxide Composition Cavity Base/Liner

**IMB Safety Notice: SN2011(19)  
Circulation Date: 10 August 2011**

**MANUFACTURER/SUPPLIER**  
DENTSPLY Caulk, USA.

**TARGET GROUPS**  
Dental Practitioners  
Distributors

**ISSUE**  
DENTSPLY has become aware that certain lots of Dycal may exhibit faster setting times than is normal for these products.

**BACKGROUND**  
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.

**ACTION OR RECOMMENDATIONS**  
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.

## ENQUIRIES

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

Mr. Torsten Riedel  
Divisional Complaint Officer / Quality Assurance

# S A F E T Y

## NOTICE

DENTSPLY DeTrey GmbH  
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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](mailto:vigilance@imb.ie)  
Website: [www.imb.ie](http://www.imb.ie)