

衛生署
醫療儀器管制辦公室

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DEPARTMENT OF HEALTH
MEDICAL DEVICE CONTROL OFFICE

ROOM 3101, 31/F., HOPEWELL CENTRE,
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本署檔號 OUR REF. S/F(90) in DH/MDCO/20-5/8

來函檔號 YOUR REF.:

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27 June 2011

Dear Dentist,

Recall of Pentron Clinical 37% Phosphoric Acid Etching Gel

We would like to bring to your attention that the Department of Health (DH) received an alert on 27 June 2011 concerning a voluntary recall of 37% Phosphoric Acid Etching Gel manufactured by Pentron Clinical because of the product quality.

DH is notified of the recall by the product's manufacturer, Pentron Clinical. Pentron Clinical reports two separate events that have occurred. The first instance is the product continues to extrude out of the syringe even after pressure is no longer applied. The second instance is due to misformulation of the affected product, which contains higher percentage of phosphoric acid than that indicated on the label. Pentron Clinical claims neither of these issues affects the efficacy of the products.

According to the manufacturer, affected products will have expiry dates between April 2011 and April 2015. The affected products are sold as individual syringes or contained in kits. Please refer to the following tables for the details:

Part number	Description of Affected Product (All Lots with Expiration Dates Between April 2011 and April 2015)
T06	37% Etching Gel – 1ml syringe
T06A	37% Etching Gel – 1ml syringe 20pk
T06B	37% Etching Gel – 1ml syringe 50pk
N01H	37% Etching Gel – 3ml syringe
N01IB	37% Etching Gel – 5ml syringe

Part Number	Kits That Contain Affected Product
N01	Bon-It Kit
N01I	Bond-1 Primer/Adhesive Kit
N04	Lute-It with Bond-1 Kit
N04B	Lute-It with Bond-1 Intro Kit
N06K	Mojo Veneer Cement Kit
N10	Protect-It Kit
N11W	Flow-It with Bond-1 Kit
N15S	Alert Syringe Kit
N33	Cement-It Universal C&B Kit
N33N	Cement-It Universal C&B w/NanoBond Kit
N55	NanoBond Kit

If you have the affected products, please contact your distributor for arrangement of a quick return and replacement.

Yours faithfully,



(Dr Addi CHAN)
for Director of Health