

3M Australia Pty Limited
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21 September 2015

Dear customer,

MEDICAL DEVICE RECALL

Lower Left buccal tubes labelled as lower right

RN: 2015-RN-00937-1

UNITEK VICTORY MINI TUBE LOWER LEFT BUCCAL TUBE, PACK OF 5:

Catalogue number: 3067-8373; Batch number: GQ9SZ-0005; ARTG 99491;

Product Class IIa GMDN [31759] Orthodontic appliance, tube

3M Australia Pty Ltd following advice by the manufacturer 3M Healthcare Group, (Monrovia, CA, United States) and after consultation with the Therapeutic Goods Administration, is recalling Unitek Victory Mini Tube_Lower Left Buccal Tube pack of 5 - batch GQ9SZ-0005. No other batches or pack sizes of this product are affected by this recall.

Due to Operator error, the labelling for this specific batch is incorrect. The notation on the blister lid shows the contents to be a lower right buccal tube, when the blister actually contains a lower left buccal tube. The catalogue number and batch number are correct and the outer box labelling is correct. The orthodontist /staff can easily identify the problem as soon as they open the blister.

Our records show that you received one pack of the affected product. Please inspect your stocks and quarantine the unit from the above batch numbers, and complete the attached Reply Form returning it to 3M Australia so that we may arrange to recover your stock and either replacement stock or a credit note issued. Please complete the Reply Form even if you have no stock that is subject to recall, as we require this information to reconcile this process.

If any of the recalled stock has been transferred from your practice to another, please immediately let the recipient know of the recall. Please also mark this on the reply form to us so that we can make contact with the practice accordingly. 3M sincerely regrets any inconvenience caused to your practice. Please contact [REDACTED] (Marketing Manager) on [REDACTED] for further inquiries.

Yours Sincerely

[REDACTED]

Marketing Manager, 3M Australia Pty Ltd
Attachment – fax back reply form