

3M ESPE
Dental Products

3M Center
2510 Conway Ave
St. Paul, MN 55144-1000
651 733 1110

3M ESPE

4 June, 2013

Subject: Voluntary Recall # 300517437006052013003-R

3M™ ESPE™ Unitek™ Primary Stainless Steel Crowns – Series UR4
Product Code 902150 (Kit)

- Lot Codes N484233 and N463186

Product Code 900224 (Refill)

- Lot codes N466509 and N473723

Dear Distributor:

Our records indicate that you have received Unitek Primary Stainless Steel Crowns from one of the lots listed above. This letter is to inform you that this product has been mislabeled. We apologize for any inconvenience this may cause you.

Background:

The subject lots of UR4 crown kits and refills contain LL3 crowns which are incorrectly labeled as UR4 crowns.

No potential health risk is expected from this labeling error because dental professionals are easily able to differentiate left-side crowns from right-side crowns during placement.

Recall Procedure:

We ask that you review your inventory of Unitek Stainless Steel Crowns for products from these lot numbers. If you identify product from these lots in your inventory, please quarantine the product and do not further distribute. To initiate product return and replacement, call Customer Service at 3M ESPE Dental Products at 1-800-237-1650.

If you have shipped any product from these lots to your customers we ask that you contact them to inform them of this voluntary recall. We have prepared a letter (Attachment 1) that is to be used in your communication. Please return any product recovered from your customers to 3M ESPE. You may initiate the return process by contacting us at 1-800-634-2249.



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Again, we apologize for any inconvenience this situation may cause you. If you have additional questions regarding this recall, you can contact me by phone at 651-733-7767 or, via email, at wdonovan@mmm.com.



William J. Donovan
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3M ESPE Dental Products Division

