



## Urgent Field Safety Notice: Discus Dental, LLC Relief ACP Oral Care Gel

October [REDACTED], 2014

Customer name <>

Address

Customer ID# <>

Re: Relief ACP Oral Care Gel

Dear Customer,

Our records indicate that you have purchased Relief ACP Oral Care Gel or product(s) containing Relief ACP (Amorphous Calcium Phosphate) Oral Care Gel labeled with the lot numbers provided on the attached listing. Product sold by Discus Dental after April 1, 2014 with those lot numbers were inadvertently filled with hydrogen peroxide teeth whitening gel (6% concentration as dispensed) on one side of the dual barrel syringe instead of the intended component (phosphate gel).

Consequently, use of this product by patients may result in a neutral effect or increased sensitivity. There have been no reported serious adverse health consequences from using this product.

We are asking for your cooperation to please cease distribution of this product immediately and contact your customers who may have received this product from April 1, 2014. Customers who are still in possession of Relief ACP Oral Care Gel should return their affected product.

Discus Dental is offering a no-cost replacement for all affected product, including free shipping. To remedy the situation we are requesting that you take the following steps:

- (1) Contact your customers who have received affected product after April 1, 2014 either by letter or telephone, and instruct them to cease use of the product immediately and return any remaining affected product.
- (2) Please use Attachment A: Product Shipped, Acknowledgement and Response Form to document the quantity of product being returned to Discus Dental LLC from you and your customers. Email completed form to [REDACTED].
- (3) Please contact Discus Dental customer service at [REDACTED] if you have any questions and to arrange for replacement products and a prepaid return shipping label.



**Picture of Product:**



Hydrogen peroxide teeth whitening gel  
(6% concentration as dispensed) on one  
side of syringe

**Location of Lot Number and SKU:**

Not all products sold contained affected lots of syringes. Please verify the lots in your stock by checking the barcode label on product package and confirm affected lots listed in the attachment A.



Discus Dental has been providing the Dental Professional community quality oral care services and solutions for 25 years. Rest assured we have implemented enhanced controls, including chemical verification testing of all products, to prevent any future reoccurrence.

Thank you for your continued partnership and for taking the suggested actions as soon as possible.

Sincerely,

Discus Dental, LLC  
Joe Yabuki  
Sr. Director, Quality & Regulatory Affairs



**Attachment A**  
**Product Shipped, Acknowledgement and Response**

Please complete the following and return to **xxx.xxx.xxxx.**

Our records indicate that you have purchased the following affected products.

Please indicate, within this table, the quantity of product that has been used or product being returned to Discus Dental.

Product Description	SKU#	Lot #	Date Shipped	Qty. Shipped	Qty. Used	Qty. Returned
Pre Filled by Discus						

If you have provided any affected product to your customers, please contact them.

We have requested our patient to return affected product to us.

**Customer Name** <>  
**Address**  
**Customer ID#** <>

Completed by:

Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_