



June 2, 2014

ALMADEN PLAZA DENTAL / HALEH KARIMIAN  
5353 ALMADEN PLAZA WAY  
SAN JOSE, CA 95118

**URGENT: MEDICAL DEVICE RECALL**

Dear ALMADEN PLAZA DENTAL / HALEH KARIMIAN:

Kerr Corporation is recalling one (1) lot of **Tytin Regular Set**, some of which was shipped to your office from November 2013 to February 2014.

We have received complaints that the amalgam may set faster than specified in the Directions for Use. This set time discrepancy may cause the product to set before there is an opportunity to place it in the preparation or complete the carving process. There is a low risk associated with the use of this product in that there would be a possible need to remove the set amalgam from the preparation and repeat the procedure.

The following table lists the affected part and lot numbers. Please review this table to determine if you have any of the affected product in your inventory.

Product Description	Part Numbers	Lot Number
Tytin – Regular Set, Double Spill – 50 capsules	29948	3-1294

**If you have any of the affected product listed above please contact Kerr Customer Care at 1-800-537-7123 to receive an RMA number.** The RMA will allow for a quick return and replacement or credit.

If you are an authorized Kerr distributor, we request that you identify those customers that may have been shipped the affected product lot and contact these customers to inform them of this issue within forty-eight (48) hours of receipt of this notification in order to retrieve their affected product.

If you or your patients have experienced an injury as a result of the affected products noted in this recall communication, you may voluntarily report the incident to the FDA through the MEDWATCH reporting system at the following:

<http://www.fda.gov/Safety/MedWatch/HowToReport/ucm053074.htm>

Kerr sincerely apologizes for the inconvenience this situation causes you and your customers.

Thank you for your patience and support.

Sincerely Yours,

Regulatory Affairs Manager, Compliance

ALMADEN PLAZA DENTAL / HALEH KARIMIAN  
5353 ALMADEN PLAZA WAY  
SAN JOSE, CA 95118

## TYTIN REGULAR SET Acknowledgement and Recall Return Form

Product Description	Part Numbers	Lot Number
Tytin – Regular Set, Double Spill – 50 capsules	29948	3-1294

- We acknowledge receipt of the Tytin Regular Set Recall Notification. We have checked our inventory and were able to locate one or more units of the above-mentioned product. We will be returning the following quantity to Kerr Corporation.***

***Authorized Kerr Distributors:*** Additionally, we acknowledge that we will identify those customers that may have been shipped the affected product lot and contact these customers within forty-eight (48) hours of receipt of this notification in order to recover their affected product.

Quantity Returned

- We acknowledge receipt of the Tytin Regular Set Recall Notification. We have checked our inventory and were unable to locate any of the above-mentioned product.***

***Authorized Kerr Distributors:*** Additionally, we acknowledge that we will identify those customers that may have been shipped the affected product lot and contact these customers within forty-eight (48) hours of receipt of this notification in order to recover their affected product.

\_\_\_\_\_  
Contact Person (Please Print)

\_\_\_\_\_  
Facility

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

**WE ALSO KINDLY REQUEST YOUR COOPERATION IN FAXING THIS  
ACKNOWLEDGEMENT FORM TO THE FOLLOWING NUMBER TO  
CONFIRM YOUR RECEIPT OF THIS NOTIFICATION WHETHER OR NOT  
YOU HAVE ANY AFFECTED PRODUCT.**

**714-288-4605**