

Customer Name/Address

Urgent Field Safety Notice

MEDICAL DEVICE RECALL

**TF Adaptive Gutta Percha
Mislabeling**

[DATE]

Dear Valued Customer:

Details on affected devices:

KerrHawe is voluntarily recalling one (1) lot of **TF Adaptive Gutta Percha Point Size SM3-50pk** which may have been shipped to your office from January 2015 to January 2016.

Product	Part Number	Lot Numbers
TF Adaptive Gutta Percha Point Size SM3-50 pk	815-1541	GE15011637

Description of the problem:

The product's outer package correctly identifies the product as the SM3-sized gutta percha point. However, it has been brought to our attention that an inner generic label incorrectly identifies the product as ML3. If doctors refer to the outer label as the reference for the size of gutta percha point, the doctor should encounter no sizing discrepancy between the file used to shape the canal and the gutta percha point used to obturate it. If a doctor, however, removes the cover of the tray and only refers to the inner package label, he could mistakenly match the gutta percha point to the wrong file size (ML3). In this remote case, the product (SM3 gutta percha point) will not properly fill the canal due to its smaller size and can result in the Gutta Percha slipping past the apex of the root.

Advise on action to be taken by the user:

If you have any of the affected product listed in the table above, please stop using the product and return it to KerrHawe. Contact **KerrHawe Customer Care at 00800 41 05 05 00 to receive an RMA number**. The RMA will allow for a quick return and replacement or credit.

KERRHAWE KINDLY REQUESTS YOUR COOPERATION IN COMPLETING AND FAXING BACK THE ENCLOSED RECALL REPLY FORM IN ORDER TO CONFIRM YOUR RECEIPT OF THIS RECALL NOTIFICATION REGARDLESS OF WHETHER YOU HAVE ANY PRODUCT IN YOUR INVENTORY.

If you are an authorized KerrHawe distributor, we request that you identify those customers that may have been shipped the affected product and contact those customers within forty-

eight (48) hours of receipt of this recall notification to inform them of the issue and retrieve their affected product.

Transmission of this Recall Communication:

Kindly pass this notice on to all those within your organization who need to be aware of this Recall Communication. Additionally, please pass this notice to any organization where the affected TF Adaptive Gutta Percha product may have been shipped.

This field safety notice is being conducted in cooperation with EU competent authorities for KerrHawe's authorized representative and in the countries where this FSCA is has been reported.

We sincerely apologize for the inconvenience this causes you and your patients.

Your cooperation in this matter is greatly appreciated.

Thank you for your patience and support.

Sincerely,

Suzette Rampair- Johnson
Quality System Manager

Customer Name/Address

RECALL RETURN FORM

Product Description

TF Adaptive Gutta Percha

Product	Part Number	Lot Numbers
TF Adaptive Gutta Percha Point Size SM3-50 pk	815-1541	GE15011637

- We acknowledge receipt of the TF Adaptive Gutta Percha 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 KerrHawe.***

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 TF Adaptive Gutta Percha 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

**PLEASE FAX THIS ACKNOWLEDGEMENT FORM TO THE FOLLOWING NUMBER
REGARDLESS OF WHETHER YOU HAVE ANY PRODUCT TO RETURN.**

00800 41 05 05 14