Date

Address

URGENT: MEDICAL DEVICE RECALL

Dear Customer:

SybronEndo Corporation would like to inform you of a manufacturing issue with 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.

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.

The following table identifies the lot number included in the scope of this notification.

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

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

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

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

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

Thank you for your patience and support.

Sincerely Yours,

Quality Systems Manager, Quality Assurance

Customer Name
Customer Address

TF Adaptive Gutta Percha Point Size SM3-50 pk
Recall Return/Acknowledgement Form

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 Point Size SM3-50 pk Recall Notification. We have checked our inventory and were able to locate one or more of the above-mentioned product. We will be returning the product to SybronEndo Corporation.***

Authorized SybronEndo 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 inform them of them of the option to return their affected product.*

Quantity being returned

☐ ***We acknowledge receipt of the TF Adaptive Gutta Percha Point Size SM3-50 pk Recall Notification. We have checked our inventory and were <u>unable</u> to locate any of the above-mentioned product.***

Authorized SybronEndo 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 inform them of this issue and 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 RECEIPT OF THIS NOTIFICATION WHETHER OR NOT YOU HAVE ANY AFFECTED PRODUCT.

909-962-5605