

**Urgent Field Safety Notice**

**MEDICAL DEVICE RECALL**

**Elements Gutta Percha Cartridge Kit and the Elements RealSeal Cartridge Kit Recall  
Due to Manufacturing Error**

November 11, 2009

**Customer Name/Address**

Dear **Customer Name:**

**Details on affected devices:**

SybronEndo would like to inform you of a manufacturing error involving the following lots of the Elements Gutta Percha Cartridge Kit and the Elements RealSeal Cartridge Kit that our records show may have shipped to your address between May and September 2009.

<b>Part Number</b>	<b>Lot Number(s)</b>
972-1002	06 0959663
972-1003	06 0957595
972-2001	07 0987641 08 0992277
972-2002	05 0941553 05 0948690 06 0955241 07 0977947 07 0987642 08 0992278 08 0998612

**Description of the problem:**

During the manufacturing process of the affected units, the molding process resulted in lock nuts that did not have the level of acceptability required, and therefore, may not withstand the pressures exhibited by the Elements Obturation Unit with which the cartridges are used. More specifically, there exists a possibility that if the lock nut were to fail, the cartridge could fall out onto patients or users and could cause a burn.

**Advise on action to be taken by the user:**

SybronEndo is requesting your cooperation in returning the affected lot numbers of the products listed in the table above. Any product, which you have in stock will be replaced at no charge or credited to your account. Please contact Sybron Endo Customer Service 00800 3032 302 directly to handle the arrangements of a quick

return and replacement. The affected product should be returned to SybronEndo at the following address:

**Ormco B.V.  
Basicweg 20  
3821 BR Amersfoort  
The Netherlands**

Please label your returned product "RECALLED PRODUCT Attention: Customer Returns". In addition, we ask for your assistance in completing the enclosed *Return Form* and returning it by fax to 00800 5000 4000

**Transmission of this Field Safety Notice:**

Kindly pass this notice on to all those within your organization who need to be aware of the manufacturing error as well as to any organization where the Elements Gutta Percha Cartridge Kit and the Elements RealSeal Cartridge Kit have been transferred, if applicable. If you have any questions, please contact SybronEndo Customer Service at 00800 3032 3032.

We sincerely apologize for the inconvenience this causes you and your patients. SybronEndo continues to strive to be a leader in quality products and we have made these revisions to better improve our service.

Thank you for your patience and support.

Sincerely,

A large black rectangular redaction box covering the signature of the sender.A smaller black rectangular redaction box covering the name of the sender.

Director, Regulatory Affairs

Distributor Name/Address

**RECALL ACKNOWLEDGEMENT/RETURN FORM**

Product Description

**Elements Gutta Percha and RealSeal Cartridge Kits**

Part Number	Lot Number(s)
972-1002	06 0959663
972-1003	06 0957595
972-2001	07 0987641 08 0992277
972-2002	05 0941553 05 0948690 06 0955241 07 0977947 07 0987642 08 0992278 08 0998612

**We acknowledge receipt of the Elements Gutta Percha and RealSeal Cartridge Kits 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 following quantity to SybronEndo.**

Lot Number	Items and Quantity Returned

**We acknowledge receipt of the Elements Gutta Percha and RealSeal Cartridge Kits Recall notification. We have checked our inventory and were unable to locate any of the above-mentioned product.**

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

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

Please return this form and any affected product by mail to:

Ormco B.V.  
Basicweg 20  
3821 Br Amersfoort  
The Netherlands

**Additionally, please fax this form to the following number:  
00800 5000 4000**