



URGENT: MEDICAL DEVICE RECALL
Elements Obturation Unit with Buchanan Heat Pluggers

December 27, 2017

Dear Customer,

The purpose of this letter is to advise you that Sybron Endo Corporation (hereafter referred as Sybron Endo) is providing an initial voluntary recall notice for the Buchanan Heat Pluggers only when used with the Elements Obturation Unit (EOU). Affected part numbers are listed in table below. Sybron Endo is still evaluating root cause and additional instructions will be provided once root cause is determined.

Product Name	Part Numbers
Elements Obturation Unit (EOU) respective Buchanan Heat Pluggers, and hot pulp test tip	973-0322, 952-0004, 952-0003, 952-0005, 952-0006, 952-0007, 952-0031, 973-0219 (hot pulp test tip)

ISSUE:

Sybron Endo received a recent increase in complaints relating to overheating Buchanan Heat Pluggers only while used with the Elements Obturation Unit (EOU) and not with other systems such as Elements Free or System B. When used in the EOU, the affected Buchanan Heat Pluggers exceed Sybron Endo internal specification and operating temperature specifications provided in the Instructions for Use (IFU). The heat pluggers tips are intended to heat to 200°C ± 50°C while in down-pack and hot pulp mode, 100°C ± 25°C while in Back Fill Mode and 600°C ± 100°C while in Cautery Mode. **Internal testing demonstrated that some tips may exceed 700 °C upon activation, while in any operating mode** (Down Pack, Back Fill, Hot Pulp Test and Cautery Mode). When this occurs, the screen will indicate NiTi and the tip will glow red shortly after activation.

We received 20 complaints from 2 customers since September 2017. Prior to September 2017, we received a total of 11 complaints from 11 customers for this issue since 2008 with no reported injuries. The incidence of the heat pluggers tip exceeding 700 °C appears to be low. Approximately 2% of the heat pluggers tips exceed the specification when product was tested from inventory.

RISK:

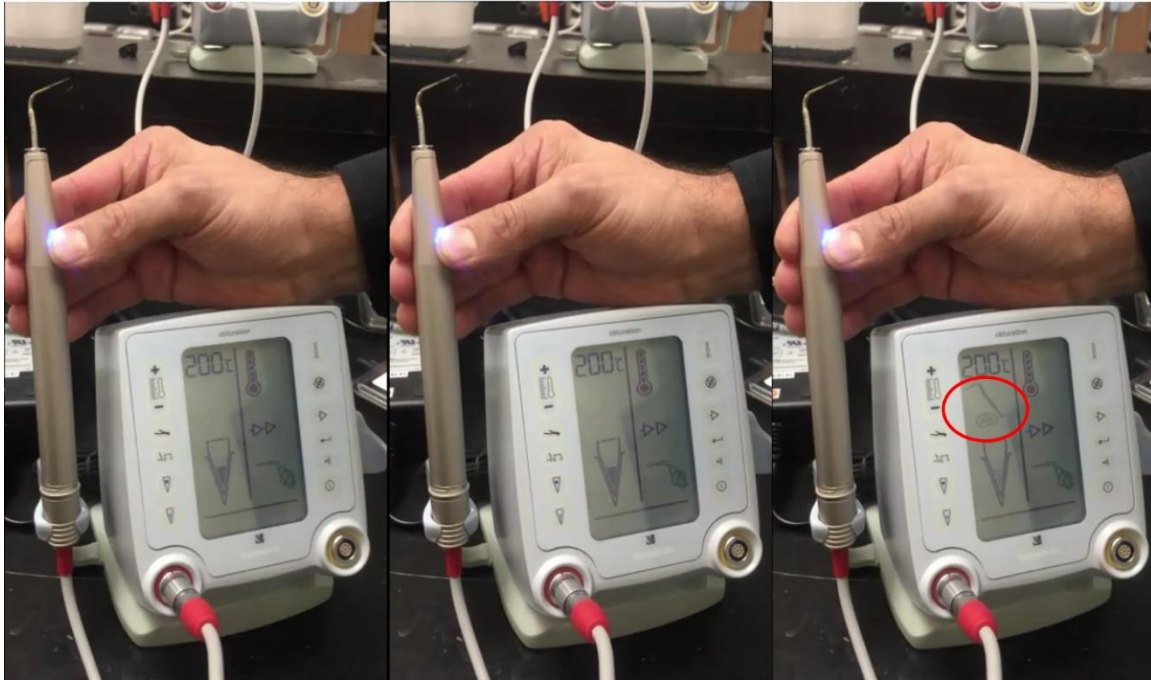
While long term health range consequences due to the increased heat of the endodontic pluggers have not been confirmed, a rise in temperature in and around the root canal can potentially cause damage to the surrounding tissues. This heating varies according to the technique used, and if the heat rises above 10°C in the human body, blood flow will be stopped and bone necrosis will occur. Therefore, a 10°C rise is the limit for preserving surrounding dental tissues. (Ericsson, Sweatman, Molyvdas, Zhang). The affected pluggers while used with EOU may reach

temperatures that could pose this risk. Because of the excellent insulating effect of the cement sealer, very low thermal conductivity and diffusivity of the dentin, lack of clinical reports or complaints of harm to patients, 9 years of clinical use of the EOU in the field, the probability of health consequences appears remote.

RECOMMENDATION:

SybronEndo requests that the customer:

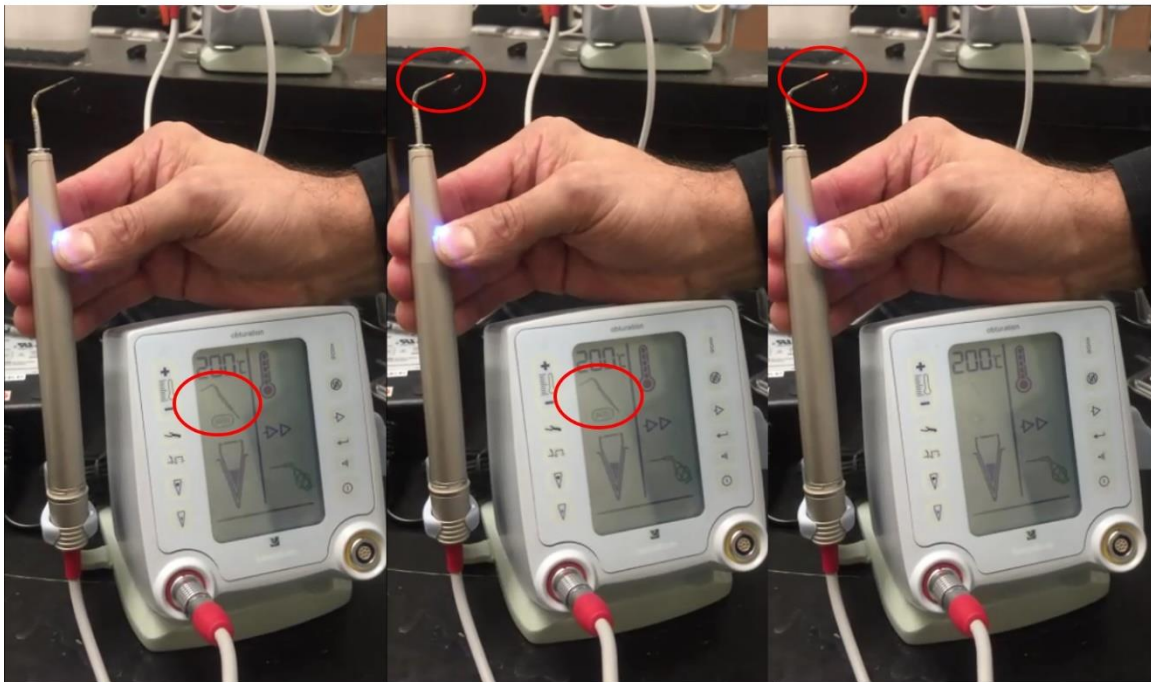
- (1) reference the EOU IFU
- (2) after turning on the device, select the desired mode, activate the System B handpiece and observe heat plugger tip and EOU console screen for 3 seconds
- (3) If in 3 seconds, the NiTi icon appears on the screen, and/or the heat plugger tip turns glowing red, the tip should not be used and should be replaced by a new one (refer to pictures below).
- (4) Evaluate the new tip in the same fashion upon activation of the heat plugger. If the NiTi icon and glowing red tip do not appear, the heat plugger may be used.
- (5) SybronEndo is requesting customers return any affected heat plugger(s).
- (6) Sybron Endo is still evaluating root cause and additional instructions will be provided once root cause is determined.



time = 0 seconds
Start of Duty Cycle

time = 1 seconds

time = 1.3 seconds
(NiTi icon appears)



time = 2 seconds

time = 3 seconds
(Red Glow is visible)

time = 4 seconds
End of Duty Cycle
(NiTi icon disappears, Red
Glow starts to diminish)

ACTIONS BY THE CUSTOMER:

- Examine current inventory for affected product and check the heat plugger to see if the NiTi icon appears and/or tip turns glowing red.
- **If you observe the NiTi icon and/or glowing red heat plugger tip, do not use heat plugger and return to SybronEndo. Please call customer care for RMA**

- Always follow the Instructions for Use when using the product
- Complete the enclosed acknowledgement form and email the form to EOU.Response@kavokerr.com within 10 business days.

Please accept our apologies for any inconvenience this may have caused. If you have any questions or require additional information, please contact our customer care department at 800-537-7123, between the hours of 7am to 5pm (PST) or send an email to KerrCustomerCare@KavoKerr.com. Adverse reactions or quality problems experienced with the use of this product may be reported to Kerr customer care, FDA or appropriate International Ministry of Health:

- <https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>, or
- Call FDA 1-800-FDA-1088

Sincerely,



Valerie Cimmarusti
Vice President, Regulatory and Design Assurance

Attachments: Acknowledgement Form



Elements Obturation Unit with Buchanan Heat Pluggers

Acknowledgement Form

Product Name	Part Numbers
Elements Obturation Unit (EOU), respective Buchanan Heat Pluggers and hot pulp test tip	973-0322, 952-0004, 952-0003, 952-0005, 952-0006, 952-0007, 952-0031, 973-0219 (hot pulp test tip)

I have read and understand the recall instructions for the Elements Obturation Unit (EOU) when used with the Buchanan Heat Pluggers Yes No

I acknowledge that current inventory has been checked for affected devices Yes No

Were there any adverse events and/or complaints of injury associated with the product? Yes No

If yes, please explain: _____

Devices determined to be affected _____

Contact Person (Please Print)

Facility

Signature

Date

Phone number

Please call customer care for RMA at 800-537-7123, between the hours of 7am to 5pm (PST) or send an email to KerrCustomerCare@KavoKerr.com.

WE ALSO KINDLY REQUEST YOUR COOPERATION IN EMAILING THIS ACKNOWLEDGEMENT FORM TO THE FOLLOWING ADDRESS TO CONFIRM RECEIPT OF THIS NOTIFICATION.

EOU.Response@kavokerr.com