ENDOCHOICE

URGENT – Medical Device Correction/Removal
Fuse 1C Colonoscopes

December, 10th, 2015

Dear

This letter is to inform you that EndoChoice, Inc. has initiated a Medical Device Correction/Removal relating to certain serial numbers of Fuse® 1C colonoscopes manufactured during a specific and defined time period. We have become aware that in rare instances, the bending section of the device may partially separate from the insertion tube. This could potentially pose a risk of tissue abrasion if it were to occur while the colonoscope is being used on a patient. This issue should not exist with devices manufactured outside the defined period or identified serial numbers.

You are receiving this information because EndoChoice has shipped to you the affected F1C colonoscopes identified by manufacturing date, as listed below:

FSC-3300-ST	F1C0668FUSE1C
FSC-3300-SL	F1C0274FUSE1CS
FSC-3300-ST	F1C0905FUSE1C
FSC-3300-ST	F1C0906FUSE1C
FSC-3300-ST	F1C0921FUSE1C

Scope services will contact you and request affected demo scopes be returned for upgrade. A loaner scope will be sent to you for each colonoscope; once received please forward the affected scope to EndoChoice GmbH. After the scope has been upgraded it will be returned to you. Once received, please return the loaner scope.

We are taking this proactive measure to reduce the risk of recurrence of this issue. The new colonoscopes represent the latest technology available, and incorporate several improvements made to the product over the last several months.

If you have questions or concerns, please contact Fuse Customer Care at +49 4101 51 73 456.

Sincerely,

Nigel Wilkinson
Vice President, Quality Assurance and Regulatory Affairs
EndoChoice, Inc