URGENT – Medical Device Correction/Removal
Fuse 1C Colonoscopes

<Address of Consignee>

December, 9th, 2015

Dear <Name of Consignee contact>,

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 one or more of the affected F1C colonoscopes, identified by manufacturing date, as listed below:

Model Number(s)	Serial Number(s)

EndoChoice will send replacement colonoscopes to you for exchanging the customer scopes. The affected scopes are to be removed from the customer facility and will be sent to EndoChoice GmbH. Ensure the colonoscope(s) being returned are properly cleaned and dried before packing.

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 5173456.

Sincerely,

[redacted]
EndoChoice, Inc