FUJIFILM

FUJIFILM Corporation
26-30, NISHIAZABU 2-CHOME, MINATO-KU,
TOKYO 106-8620 JAPAN

Dear [redacted],

This is to inform you the outline of the field correction action which FUJIFILM recently conducted in U.S.A.. We also would like to inform you of the action plan in your jurisdiction.

<Field Correction Action in Singapore>

The Instruction Manuals "Preparation and Operation" and "Cleaning , Disinfection and Storage" (for models in described in the below <Affected Models to the Field Correction>) have been revised to reflect newly validated manual cleaning and high-level disinfection procedures in accordance with FDA guidance document, Reprocessing Medical Devices in Health Care Settings: Validation Method and Labeling issued on March 17, 2015.

Accordingly, since the affected models have not been supplied to the customer in Singapore, Fujifilm expects to provide revised Instruction Manuals and new disposable distal end cleaning brushes for the customer when we installed the affected models. Due to the preparation of revised Instruction Manuals (inclusive of English translation) and production of new disposable distal end cleaning brushes, the field correction action in your jurisdiction are estimated to be implemented by May 2016. Hence we request you to refrain from doing any product demonstrations until above mentioned FSCA is implemented.

<Reason of the Action>

This action is being taken as a result of publicized reports of multi-drug resistant bacteria on certain duodenoscopes used for Endoscopic Retrograde Cholangiopancreatography (ERCP) procedures as well as Safety Communications issued by U.S. Food and Drug Administration (FDA) on February 19 and August 4, 2015. Given these reports and in an abundance of caution, Fujifilm worked with the FDA to validate the reprocessing procedures that are provided in the revised Instruction Manuals.

<Affected Models to the Field Correction>

The affected models are ED-530XT and ED-530XT8 shipped to your region.

If you have any further question, please do not hesitate to contact our Safety Officer Team under
md-safetyofficer@fujifilm.com.

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References

FDA, Design of Endoscopic Retrograde Cholangiopancreatography (ERCP) Duodenoscopes May Impede Effective Cleaning: FDA Safety Communication, 19 February 2015, available from:
http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm434871.htm

FDA, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff , 17 Mar 2015, available from:
http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM253010.pdf

FDA, Supplemental Measures to Enhance Duodenoscope Reprocessing: FDA Safety Communication, 4 August 2015, available from:
http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm454766.htm

Date 2, 8, 2016

Signature [redacted]
Safety Officer
QUALITY ASSURANCE & REGULATORY AFFAIRS DIV.
MEDICAL SYSTEM BUSINESS DIV.
FUJIFILM Corporation