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

ED-530XT
Singapore Voluntary recall strategy

Introduction: FUJIFILM ASIA PACIFIC PTE LTD (FFAP) initiated a voluntary recall of its currently distributed Duodenoscope Model ED-530XT(the subject device).
This activity has been planned through close collaboration with our headquarter Fujifilm corporation, Japan. Since there is no installation in Singapore, the mentioned model is not affected by this recall.

Contact information:

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Correction Type: FFAP is planning to execute correction by our ECN-G1735[Ver.1]

Scope: 4 demo/loaner support (not sales) ED-530XT duodenoscope in Singapore

Purpose: Pursuant to ENGINEERRING CHANGE NOTICE (ECN) ECN-G1735[Ver.1] issued by FUJI FILM corporation Japan on Feb.6 2018, the forceps elevator mechanism with O-ring seal, distal end cap, and Operation Manual of 33 distributed ED-530XT duodenoscopes are being updated to help reduce the potential risk to health that may be associated with inadequate reprocessing of the device.

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Execution Strategy

1. Notification

   FFAP has provided the Field Safety Notice (FSC) with a revised Operation manual.

2. Correction and Modification

   a. FFAP to perform the modification of our demo/loaner scope at FFAP office, Singapore.

   b. Replacement of the forceps elevator mechanism, O-ring seal, and distal end cap for all units subject to the modification is executed as Table 1, next page.

Table1. Individual Scope Modification Steps

Activities
Receipt of scope; and incoming inspection
Disassemble endoscope
Replace elevator mechanism with O-rings; apply distal end cap
Curing of distal end cap
Adjustment; final inspection

3. Reporting

   After completed all Modification, final report will be provided by FUJIFILM ASIA PACIFIC PTE LTD and FUJIFILM Corporation, Japan within a year after the start of this recall on May 7th, 2018.

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Signature [redacted]

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