

## FIELD SAFETY NOTICE

Product:

FUJIFILM - Duodenoscope Model ED-530XT

**Type of Action:**

- 1) Notification of the instruction manual revision,
- 2) Replacement of the forceps elevator mechanism and O-ring seal, replacement of the distal end cap.

Dear Customers,

FUJIFILM is issuing this Field Safety Notice for our Duodenoscope ED-530XT.

This Field Safety Notice is intended to inform you about the following:

- what the problem is
- the actions that should be taken by the customer/user

**This document contains important information for the continued safe and proper use of your equipment.**

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

### **Description of the problem**

The field corrective safety action for the ED-530XT includes replacement of the forceps elevator mechanism and O-ring seal, replacement of the distal end cap, and new Operation Manuals. The updated design and labeling were implemented in an abundance of caution to help reduce the potential risk to health that may be associated with inadequate reprocessing of the device.

FUJIFILM will provide the revised operation manual. Please follow the revised operation manual after this. Below are the main differences in the operation manual revision.

- Added the requirement for the ED-530XT to be returned to local FUJIFILM dealer or authorized service representative for inspection and replacement of the forceps elevator seal once a year to maintain safe use of the device.

### **Actions to be taken by customer/user**

- (1) According to the procedure of the revised operation manual, please conduct handling and reprocessing for the ED-530XT.
- (2) Please discard old manuals upon receipt of the new ones.

### **Actions Planned by FUJIFILM**

FUJIFILM service personnel will contact all of the medical facilities where the affected products have been installed to arrange for the replacement of target parts.



**Field Safety Notice Reference: FSN 20180116 Duodenoscope ED-530XT**

FUJIFILM is committed to providing products and services of the highest quality. Your satisfaction with FUJIFILM products and with our response to this issue is very important to us.

If you have any questions about this matter, please contact your local FUJIFILM office.

Yours sincerely,

FUJIFILM

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# FIELD SAFETY NOTICE

## Customer Feedback Form

Please complete this feedback form and fax or email it back.  
Thank you for your cooperation.

Facility Name:

Address:

ED-530XT Serial Number:

I confirm that I have received and understand the attached notice.

This notice does not apply to my facility.

The device has been transferred to another organization.

**Printed Name:**

**Position:**

**Signature:**

**Date:**

**Phone number:**

**If we have the wrong contact information about you, please correct below:**

**Facility Name:**

**Address:**

**Please FAX or email this completed form to:**