Field Safety Notice Reference: FSN 20170501 Endoscopic Ultrasonic Probe

FIELD SAFETY NOTICE

Product:

- Endoscopic Ultrasonic Probe PB2020-M

Type of Action: Notification of the instruction manual revision

Dear Customers,

FUJIFILM is issuing this Field Safety Notice for our Endoscopic Ultrasonic Probe PB2020-M.

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

FUJIFILM become aware that there is a possibility the intended reprocessing procedure may not be conducted when the current operation manual is accorded for target product. Therefore, FUJIFILM revised the operation manual to make the contents of its instructions easy to understand.

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.

- Corrected the description to make easier to understand, on the whole.
- added flushing area and increased flushing volumes of disinfectant onto the probe connector portion, in the procedure of Disinfection.

Actions to be taken by customer/user

(1) According to the procedure of the revised operation manual, please conduct cleaning and disinfecting for target product.

(2) Please discard all operation manuals of the previous version.

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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Customer Feedback Form

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

Customer/Facility Name:

Address:

Instrument 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.

Customer Name:

Position:

Signature:

Date:

Phone number:

If we have the wrong contact information about you, please correct below:
Customer/Facility Name:

Address:

Please FAX or email this completed form to: