

FIELD SAFETY NOTICE

Product:

- Endoscope EG-760R, EG-760Z, EC-760R-V/M, EC-760R-V/I, EC-760R-V/L, EC-760ZP-V/M and EC-760ZP-V/L
- Ultrasonic Endoscope EG-580UT and EG-580UR

Type of Action: Notification of the instruction manual revision

Dear Customers,

FUJIFILM is issuing this Field Safety Notice for our Endoscope types EG-760R, EG-760Z, EC-760R-V/M, EC-760R-V/I, EC-760R-V/L, EC-760ZP-V/M, EC-760ZP-V/L and Ultrasonic Endoscope EG-580UT and EG-580UR.

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

In case the cleaning brush will be damaged inside the channel during the scope cleaning, it is instructed by the operation manual to remove any residue from inside the channel using a spare brush. If residue remains inside the channel, it could be a source of infection. However, in case of the combination of the cleaning brush WB7024FW and the affected endoscope models, we become aware that residue of the cleaning brush cannot be removed in rare cases with this method.

FUJIFILM will provide the revised instruction manual "Cleaning, Disinfection and Storage".

Please follow the revised instruction manuals after this. In particular, please keep the following points in mind.

- Carefully inspect all cleaning brushes for abnormalities and/or damage prior to use and after every brushing.
- In case the cleaning brush is damaged during cleaning, and if residue is not completely removed even with the spare brush, have the endoscope repaired immediately.

Actions to be taken by customer/user

- (1) According to the procedure of the revised instruction manuals, please conduct cleaning and disinfecting for target product.
- (2) Please discard all instruction 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.

Field Safety Notice Reference: FSN 20160812 Endoscopes

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: