OLYMPUS KEYMED
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Date: 6 January 2017

URGENT: FIELD SAFETY NOTICE

Action Identification Number: **234**
Type of Action: **Field Safety Notice**

Affected Product:

OLYMPUS URF-V2 and URF-V2R URETERO-RENO VIDEOSCOPES
OLYMPUS URF-P6 and URF-P6R URETERO-RENO FIBERSCOPES

Affected serial numbers:

All serial numbers

Dear Customer

Olympus has become aware of an issue that requires your attention. This Urgent Field Safety Notice pertains to the OLYMPUS URF-V2 and URF-V2R Uretero-reno videoscopes, and URF-P6 and URF-P6R Uretero-reno fiberscopes. Our records indicate that your facility has purchased one or more of these products. The URF-V2, URF-V2R and the URF-P6, URF-P6R endoscopes are intended for use in endoscopic diagnosis and treatment within the ureter and kidney. The URF-P6 and P6R endoscopes are also intended for use in endoscopic diagnosis and treatment within the biliary tract (common bile duct and hepatic duct).

Olympus has initiated this corrective action following investigation of five adverse events on the **URF-V2 and URF-V2R** regarding the breakage of the endoscope's insertion tube bending section during surgical procedures. To date, these adverse events are associated in two cases with tissue trauma, one case of perforation, and two cases of insertion tubes which were stuck inside the patient and had to be surgically removed. Olympus is writing to advise you on this matter and to recommend action.

Regarding the **URF-P6, URF-P6R** Olympus has received complaints regarding breaks of the bending tube – none of them resulted in an adverse event.

In an effort to mitigate a potential risk to patient or user health, Olympus is notifying users of these adverse events and complaints as well as the need for careful inspection of the endoscopes prior to use in accordance with the instructions provided below.

Olympus requests you to report any patient injuries associated with Olympus endoscopes. Contact the Olympus Helpdesk on 01 426 0100.

Action Steps

Olympus requires you to take the following actions:

Inspect your inventory for the referenced devices and identify any of the specified Olympus models. Please maintain with your inventory the attached Instructions for Safe Use and conduct the following activities.

1. Please inspect the URF-V2, URF-V2R, URF-P6 and URF-P6R prior to patient use according to the enclosed Instructions for Safe Use. The URF-V2, URF-V2R and URF-P6, URF-P6R **Operation Manuals** contain the same inspection instructions in **Chapter 3.3, Inspection of the Endoscope**.

   We have added pictures and additional instructions on the enclosed Instructions for Safe Use to assist in performing this inspection.
   In particular,

   a. Please pay attention to the bending section for any evidence of protrusions from the insertion tube or abnormal bending shape, as illustrated on the enclosed Instructions.

2. Please do not use the endoscope if resistance is felt during insertion. The URF-V2, URF-V2R, URF-P6 and URF-P6R **Operation Manuals** contain the same **Warnings and Cautions for Operation in Chapter 4.1.**

   We have added a note and picture on the enclosed Instructions for Safe Use to assist in understanding the Warnings and Cautions.

   In particular,

   a. Do not angulate the endoscope with excessive force to the opposite direction of the bending direction, or utilise excessive force upon insertion.

3. Please note on the enclosed Field Safety Notice Confirmation Reply Form that you have received this Safety Notice.

4. Complete and return the attached Reply Form by **16 January 2017**. Please send the form by post, fax or a digitally scanned e-mail to:

   Ms Lynette Moran – Office Manager: Olympus Ireland
   Email: info@olympus.ie
   Fax: 01 426 0123

We appreciate your cooperation and apologise for any inconvenience this may cause. If you have any questions or would like further information, please do not hesitate to contact the Olympus Helpdesk on 01 426 0100.

Yours Sincerely

Robert Griggs

Quality and Regulatory Affairs General Manager

Enc. Field Safety Notice Confirmation Reply Form

Date: 6 January 2017

URGENT: FIELD SAFETY NOTICE CONFIRMATION REPLY FORM

Affected Product:

OLYMPUS URF-V2 and URF-V2R URETERO-RENO VIDEOSCOPES
OLYMPUS URF-P6 and URF-P6R URETERO-RENO FIBERSCOPES

Affected serial numbers: **All serial numbers**

Please send the completed and signed reply form by post, fax or a digitally scanned e-mail to:

Ms Lynette Moran – Office Manager: Olympus Ireland
Email: info@olympus.ie
Fax: 01 426 0123

Dear Ms Moran

I confirm that we have received your Field Safety Notice and the Instructions for Safe Use for the URF-V2/V2R and URF-P6/P6R endoscopes referenced above. We will share this information with all those who need to be made aware within our facility.

I understand that I need to inspect my endoscope as per the Instructions for Safe Use prior to patient use.

Name & Job Title: _____

Department: _____

Facility Name: _____

Address: _____

City: _____ County: _____

Post Code: _____Telephone number: _____