



Date: December 28, 2016

**URGENT MEDICAL DEVICE SAFETY NOTICE**

Attention: Operating Room Manager  
Risk Management Department

**RE: OLYMPUS Uretero-reno Fiberscope**  
**Models: URF-P6, URF-P6R**  
**Serial numbers: all serial numbers**

Dear Health Care Practitioner:

Olympus America Inc. ("OAI") has become aware of an issue that requires your attention. This Safety Notice pertains to the OLYMPUS URF-P6/P6R Uretero-reno fiberscopes. The URF-P6/P6R endoscopes are intended for use in endoscopic diagnosis and treatment within the ureter, kidney and biliary tract (common bile duct and hepatic duct).

OAI has received complaints on the URF-P6/P6R insertion tube, and breaks of the bending tube, but these complaints have not resulted in any known adverse events. Olympus is aware of adverse event complaints on the URF-V2/V2R endoscopes which have a similar structure to the URF-P6/P6R endoscopes. To date, the complaints on the URF-V2/V2R models are associated with tissue trauma, including one complaint of perforation, and two complaints of insertion tubes which were stuck inside the patient and had to be surgically removed.

In an effort to mitigate a potential risk to patient health, Olympus is undertaking this action to notify users of these complaints and the need for careful inspection of the endoscope prior to use in accordance with the instructions provided below.

OAI requests you to report any patient injuries associated with Olympus endoscopes. Call our Technical Assistance Center (TAC) at 1-800-848-9024, option 1 to report complaints.

**Action Steps:**

Our records indicate that your facility has purchased one or more URF-P6/P6R endoscopes. **OLYMPUS requires that you 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-P6/P6R prior to patient use as per the enclosed Instructions for Safe Use. The URF-P6/P6R Operation Manual contains 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-P6/P6R Operation Manual contains 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 utilize excessive force upon insertion.
3. Please note on the enclosed Reply Form that you have received this Safety Notice.
4. Fax the completed Reply Form to Olympus Regulatory Affairs at 484-896-7128.

You can contact our Technical Assistance Center (TAC) at 1-800-848-9024, option 1 to answer any questions.

The U.S. Food and Drug Administration is aware of this action.

OLYMPUS regrets any inconvenience from this action and fully appreciates your prompt cooperation in addressing this situation. Please do not hesitate to contact me directly at 484-896-5688 or at [laura.storms@olympus.com](mailto:laura.storms@olympus.com) if you have any questions on this matter.

Regards,



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