OLYMPUS®

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 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 if you have any questions on this matter.

Regards,

Laura Storms

Laura Storms
V.P., Regulatory Affairs & Quality Assurance
Olympus Corporation of the Americas

OLYMPUS®

Your Vision, Our Future

CE 0197

USA: CAUTION:
Federal law restricts this device to sale by or on the order of a physician.

Instructions for safe use

This instruction includes special care points for safe usage excerpted from the Instruction Manual of Olympus URF-V2/V2R and URF-P6/P6R uretero-reno endoscopes. They are particularly important and should be noted when using Olympus URF-V2/V2R and URF-P6/P6R uretero-reno endoscopes. Before using the scopes, read the "Instruction Manual" carefully and follow the instructions. If an abnormality is detected before or during usage, or the equipment is malfunctioning, do not use the equipment and contact Olympus to request repair.

Warnings and notes

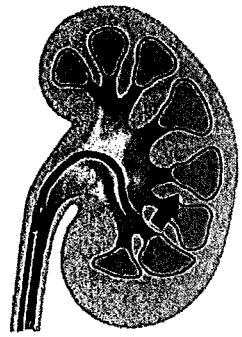
WARNING

- If significant resistance is felt during insertion due to an anatomical reason, do not insert, withdraw, or turn the insertion tube of the endoscope with excessive force. Ureter injury, bleeding, and/or perforation may occur.
- Never insert or withdraw the endoscope under any of the following conditions. Patient injury, bleeding, and/or perforation can result.
  - While the EndoTherapy accessory extends from the distal end of the endoscope (except for using an ureteral access sheath).
  - While the bending section is locked in position.
  - Insertion or withdrawal with excessive force.
- If any of the following conditions occur during an examination, immediately stop the examination and withdraw the endoscope from the patient as described in Section 5.3, "Withdrawal of the endoscope with an irregularity".
  - If any irregularity is observed with the functionality of the endoscope.
  - If the endoscopic image on the monitor disappears or freezes unexpectedly.
  - If noise, blur, or fog appear on the endoscopic image. (for URF-V2/V2R)
  - If the UP/DOWN angulation control lever does not move.
  - If the angulation control mechanism is not functioning properly.

  Continued use of the endoscope under these conditions could result in patient injury, bleeding, and/or perforation.
- If the angulation control mechanism or any other part of the system is not functioning properly, stop the procedure immediately and place the UP/DOWN angulation lock in the free "F▼" position. Then carefully withdraw the endoscope while observing the endoscopic image. If the endoscope cannot be withdrawn from the patient smoothly, do not attempt to forcibly withdraw it. Rather, withdraw the endoscope carefully. If the endoscope cannot be withdrawn from the patient, consider removing it through open surgery and take proper measures. Forcibly withdrawing the endoscope may cause patient injury, bleeding, and/or perforation. If any irregularity with the endoscope is observed, contact Olympus.
- If the endoscope or EndoTherapy accessory cannot be withdrawn from the patient smoothly, do not attempt to forcibly withdraw it. Rather, withdraw the endoscope or EndoTherapy accessory carefully. If the endoscope or EndoTherapy accessory cannot be withdrawn from the patient, consider removing it through open surgery and take proper measures. Forcibly withdrawing the endoscope or EndoTherapy accessory may cause patient injury, bleeding, and/or perforation. If any irregularity with the endoscope or EndoTherapy accessory is observed, contact Olympus.
- If the endoscope cannot be withdrawn from the ureteral access sheath smoothly, do not attempt to forcibly withdraw it. Rather, withdraw the endoscope with the ureteral access sheath. Otherwise, patient injury, bleeding, and/or perforation may result.

NOTE

- Do not operate the angulation control lever with excessive force in a narrow space to the opposite direction from the bending direction while the distal end of the endoscope is not moved. The bending section may be damaged. Check the tip position of the endoscope and the shape of the bending section using fluoroscopy, etc. Do not insert the insertion tube with excessive force and twist.
- Do not insert the insertion tube with excessive force into the ureter or calix. The bending section may be damaged.

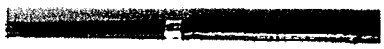


Inspection of the bending mechanism

The physician who meets the user qualifications described in the Instruction Manual should inspect the bending section of the endoscope according to the following procedures.

1. Visually inspect the bending section for no metallic parts protruding from the bending section.

OK

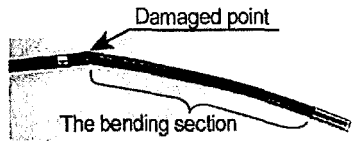


Not OK

2. Visually inspect the bending section for bends, twist, or other irregularities while the bending section remains straight.

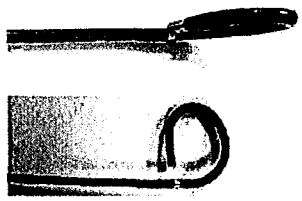
OK

Not OK



3. Visually inspect the bending section for abnormal bending shape, or other irregularities.

OK



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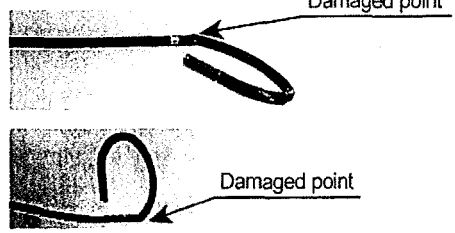

If any irregularity is observed during the inspection described in Chapter 3 of the Instruction Manual, "Preparation and Inspection" , do not use the endoscope and solve the problem as described in Section 5.2, "Troubleshooting guide" . If the problem still cannot be resolved, send the endoscope to Olympus for repair as described in Section 5.4, "Returning the endoscope for repair" . Also, should any irregularity be observed while using the endoscope, stop using it immediately and withdraw the endoscope from the patient as described Section 5.3, "Withdrawal of the endoscope with an irregularity" .

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OLYMPUS

OLYMPUS URGENT MEDICAL DEVICE SAFETY NOTICE
REPLY FORM

Affected Models: URF-P6/P6R Uretero-reno fiberscopes (URF-P6/P6R)

Serial Numbers - all serial numbers

By submitting this reply form I acknowledge that I have received the Instructions for Safe Use for the URF-P6/P6R endoscopes referenced above.

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

Facility: (Please do not abbreviate)

_____

Address:

_____

City:

_____

State: _____ Postal Code: _____

Your Name: _____

Your Phone Number: _____

Please fax this completed reply form to Olympus Regulatory Affairs Department at facsimile 484-896-7128

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