January 17 2018

URGENT MEDICAL DEVICE REMOVAL ACTION

ATTENTION: Urology Department
Re: OLYMPUS URF-P6/P6R URETERO-RENO FIBERSCOPE
Serial Numbers: All serial numbers

Dear Health Care Professional:

Olympus America Inc. (OAI) is writing to inform you of a removal action of all URF-P6/P6R Uretero-reno fiberscopes and replacement with new URF-P6/P6R fiberscopes in order to correct for bending mechanism complaints. This action is a follow-up to a Medical Device Safety Notice issued to your facility in December 2016. The URF-P6/P6R fiberscopes are intended for use in endoscopic diagnosis and treatment within the ureter, kidney and biliary tract (common bile duct and hepatic duct).

This removal and replacement action is being taken in response to complaints regarding the breakage of the endoscope's insertion tube bending section during surgical procedures. To date, one complaint is associated with tissue trauma and an insertion tubes which was stuck inside the patient and had to be surgically removed.

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.

In December 2016 OAI notified customers of the potential for breakage of the fiberscope's insertion tube and the need for inspection of the URF-P6/P6R prior to patient use as per the enclosed Instructions for Safe Use. OAI will now be replacing your existing URF-P6/P6R fiberscope(s) with a new URF-P6/P6R fiberscope(s) which has a modified bending mechanism pending 510(k) clearance. The U.S. Food and Drug Administration is aware of this action. You can continue to use your existing URF-P6/P6R fiberscope following the Instructions for Safe Use, which are enclosed in this letter, until you receive the new replacement fiberscope. You must return your current URF-P6/P6R fiberscopes so that we can exchange it with the new URF-P6/P6R fiberscopes.

Return of the enclosed questionnaire will be deemed to be a request for a new replacement URF-P6/P6R fiberscope(s).

New URF-P6/P6R fiberscopes manufactured with the new bending design will have a serial number which has a "3" as the third digit and are not included in this corrective action.

Action Steps:
Our records indicate your facility has purchased one or more URF-P6/P6R fiberscope(s). **Olympus requests you to take the following immediate action:**

1. Inspect your inventory and identify any URF-P6/P6R models.
2. Olympus will contact your facility to make arrangements for return of your URF-P6/P6R fiberscope(s) for the device exchange. You will be provided instructions on returning the URF-P6/P6R for this exchange

3. Olympus has discontinued previously distributed copies of the URF-P6/P6R Reprocessing Manual and the Operation Manual. Inspect your inventory of the Reprocessing Manual and the Operation Manual, and **discard** any existing inventory of the URF-P6/P6R Reprocessing Manual and the Operation Manual.
4. Implement use of the enclosed Reprocessing Manual which recommends only sterilization methods, and the enclosed Operation Manual.
5. Ensure all reprocessing personnel are completely knowledgeable and thoroughly trained on the new reprocessing instructions in the new Reprocessing Manual.
6. If you may have further distributed the URF-P6/P6R, please identify your customers, notify them at once of this product recall, and appropriately document your notification process. Your notification to your customers may be enhanced by including a copy of this recall notification letter.
7. Please indicate on the enclosed questionnaire that you have received this notification. Return of the enclosed questionnaire will be deemed to be a request for a new replacement URF-P6/P6R fiberscope(s). Fax the completed form to 484-896-7128.

Olympus has updated the URF-P6/P6R Reprocessing Manual and the Operation Manual with **a new Reprocessing Manual and a new Operation Manual**. The new Reprocessing Manual contains new information on the reprocessing workflow. Olympus has removed high level disinfection (HLD) as a recommended reprocessing method for the URF-P6/P6R as the fiberscope is used in sterile areas such as the ureter and kidneys. Therefore, the new Reprocessing manual recommends only sterilization methods. The new Operation manual is also revised to correspond to removing the HLD method from the reprocessing workflow as well as to include the Instructions for Safe Use. The new Reprocessing Manual has version number RC178905 on the back cover, lower left corner. The new Operation Manual has version number RC178807 on the back cover, lower left corner.

Olympus regrets any inconvenience and fully appreciates your prompt cooperation in addressing this situation. If you have any questions or concerns, please do not hesitate to contact me directly at 484-896-5688 or at laura.storms@olympus.com.

Sincerely,

Laura Storms

Laura Storms
V.P., Regulatory Affairs & Quality Assurance.

OLYMPUS

URGENT: MEDICAL DEVICE REMOVAL ACTION REPLY FORM

Please fax this completed Reply Form to Olympus Regulatory Affairs Department at 484-896-7128

OLYMPUS URF-P6/P6R URETERO-RENO FIBERSCOPE

OLYMPUS URF-V2/V2R URETERO-RENO VIDEOSCOPE

Serial Numbers: All serial numbers

I have received the medical device removal action notice on the URF scopes referenced above. I understand that I need to inspect my inventory and return any affected devices I have identified.

Return of this questionnaire will be considered a request for a replacement URF scope(s).

I plan on returning the following quantity of URF-P6 scope(s) for replacement: _____

I plan on returning the following quantity of URF-P6R scope(s) for replacement: _____

I plan on returning the following quantity of URF-V2 scope(s) for replacement: _____

I plan on returning the following quantity of URF-V2R scope(s) for replacement: _____

If you do not want to replace your URF scopes, check the box below.

☐ No Replacement of my URF scopes is required.

Date: _____

Facility / Hospital Name (please do not abbreviate):

_____

Address:

_____

City / State/ Zip Code:

_____

Print Your Name:

_____

Your Phone Number:

_____