



January 17 2018

**URGENT MEDICAL DEVICE REMOVAL ACTION**

**ATTENTION: Urology Department**  
**Re: OLYMPUS URF-V2/V2R URETERO-RENO VIDEOSCOPE**  
**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-V2/V2R Uretero-reno videoscopes and replacement with new URF-V2/V2R videoscopes 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-V2/V2R videoscopes are intended for use in endoscopic diagnosis and treatment within the ureter and kidney.

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, some of these complaints are associated with tissue trauma, including one complaint of perforation, and three complaints of insertion tubes which were 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 videoscope's insertion tube and the need for inspection of the URF-V2/V2R prior to patient use as per the enclosed Instructions for Safe Use. OAI will now be replacing your existing URF-V2/V2R videoscope(s) with a new URF-V2/V2R videoscope(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-V2/V2R videoscope following the Instructions for Safe Use, which are enclosed in this letter, until you receive the new replacement videoscope. You must return your current URF-V2/V2R videoscopes so that we can exchange it with the new URF-V2/V2R videoscopes.

New URF-V2/V2R videoscopes manufactured with the new bending design will have a serial number which has a "2" 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-V2/V2R videoscope(s). **Olympus requests you to take the following immediate action:**

1. Inspect your inventory and identify any URF-V2/V2R models.
2. Olympus will contact your facility to make arrangements for return of your URF-V2/V2R videoscope(s) for the device exchange. You will be provided instructions on returning the URF-V2/V2R for this exchange
3. Olympus has discontinued previously distributed copies of the URF-V2/V2R 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-V2/V2R 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-V2/V2R, 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-V2/V2R videoscope(s). Fax the completed form to 484-896-7128.

Olympus has updated the URF-V2/V2R 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-V2/V2R as the videoscope 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 RC096905 on the back cover, lower left corner. The new Operation Manual has version number RC096709 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](mailto:laura.storms@olympus.com).

Sincerely,



Laura Storms

V.P., Regulatory Affairs & Quality Assurance.



**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:  
\_\_\_\_\_