Olympus Reference: QIL 150-017

Date: January XX 2018

URGENT INFORMATIOM ABOUT A MEDICAL DEVICE RECALL:
BENDING MECHANISM REPLACEMENT FOR THE URETERO-RENO FIBERSCOPES

ATTENTION: Urology Department

Re: URETERO-RENO FIBERSCOPE
Model: OLYMPUS URF-P6, URF-P6R
Serial Numbers: All serial numbers

Dear Health Care Professional:

[Name of your company; e.g. Olympus Germany. ("ODE")] is writing to inform you of a recall of all OLYMPUS URF-P6, URF-P6R Uretero-reno fiberscope(s). This action is a follow-up to a Medical Device Safety Notice issued to your facility in January 2017.

Olympus has become aware of an issue that requires your attention. This Urgent Field Safety Notice pertains to the OLYMPUS URF-P6 and URF-P6R Uretero-reno fiberscope(s) and our records indicate that your facility has purchased one or more of these products. These products 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 as an Olympus decision in response to complaints regarding the breakage of the endoscope's insertion tube bending section during surgical procedures. Olympus 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. However, 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 three complaints of insertion tubes which were stuck inside the patient and had to be surgically removed.

In January 2017 [Name of your company] notified customers of the potential for breakage of the endoscope's insertion tube and the need for inspection of the URF-P6/P6R prior to patient use as per enclosed Instructions for Safe Use. [Name of your company] will now be replacing your existing URF-P6/P6R Uretero-reno fiberscope(s) with a new URF-P6/P6R Uretero-reno fiberscope(s) which has a modified bending mechanism.
New URF-P6/P6R Uretero-reno 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.
[Name of your company; e.g. Olympus Germany. ("ODE")] **will contact your facility to make arrangements for return of your URF-P6/P6R Uretero-reno fiberscope(s) for the device exchange.**
You can continue to use the URF-P6/P6R Uretero-reno fiberscope following the Instructions for Safe Use, which are enclosed in this letter. In the meantime you can still send in the devices for repair.

[Name of your company; e.g. Olympus Germany. ("ODE)]requests you to report any patient injuries associated with Olympus endoscopes. Call our [your contact number].

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

1. Inspect your inventory and identify any URF-P6/P6R models.
2. **[Name of your company] will contact your facility within the next ten months to make arrangements for return of your URF-P6/P6R uretero fiberscope(s) for the device exchange.** You will be provided instructions on returning the URF-P6/P6R for this exchange. You do not need to proactively contact Olympus and can continue to use your existing URF-P6/P6R Uretero fiberscope(s).
3. 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.
4. Please indicate on the enclosed questionnaire that you have received this notification. Additionally please fill the number of the affected URF-P6/P6R in your inventory. Fax the completed form to [your contact number].

[Name of your competent authority notified of this action; e.g. The BfArM] is aware of this action.

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 [contact number] or by e-mail at [representative email address].

Sincerely,

REPLY FORM - QIL 150-017

OLYMPUS URGENT INFORMATIOM ABOUT A MEDICAL DEVICE RECALL

Affected Model: URF-V2/V2R Uretero-reno videoscope
URF-P6/P6R Uretero-reno fiberscope

Serial Numbers - All Serial Numbers manufactured prior to November 2017

I herewith confirm that I have received the Urgent Medical Device Removal and Corrective Action Notice on the URF-V2/V2R Uretero-reno videoscope(s) and/or URF-P6/P6R Uretero-reno fiberscope(s) referenced above.
I understand that I need to inspect my inventory to identify any URF-V2/V2R and URF-P6/P6R models.

Olympus will contact your facility to make arrangements for return of your URF-V2/V2R Uretero-reno videoscope(s) and URF-P6/P6R Uretero-reno fiberscope(s) for the device exchange within the next ten months. You will be provided instructions on returning the URF-V2/V2R and URF-P6/P6R for this exchange.

Please state in the below table all the Serialnumbers of each Model you have available in your facility:

Model Name (e.g. URF-V2)	**Serialnumber**
URF-V2	
URF-V2R	
URF-P6	
URF-P6R	

Facility: (Please do not abbreviate)

_____

Address:

_____

City:

_____

State: _____ Postal Code: _____

Your Name: _____

Your Phone number: _____

Please fax this completed reply form to Olympus at [contact number]