



Olympus Reference: QIL 150-017

Date: January XX 2018

**URGENT INFORMATION ABOUT A MEDICAL DEVICE RECALL:
BENDING MECHANISM REPLACEMENT FOR THE URETERO-RENO VIDEOSCOPIES**

ATTENTION: Urology Department

Re: URETERO-RENO VIDEOSCOPE

Model: OLYMPUS URF-V2, URF-V2R

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-V2, URF-V2R Uretero-reno videoscopes. 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-V2 and URF-V2R Uretero-reno videoscopes 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 and kidney.

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. 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.

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-V2/V2R prior to patient use as per enclosed Instructions for Safe Use. [Name of your company] will now be replacing your existing URF-V2/V2R Uretero-reno videoscope(s) with a new URF-V2/V2R Uretero-reno videoscope(s) which has a modified bending mechanism.

New URF-V2/V2R Uretero-reno 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.

[Name of your company; e.g. Olympus Germany. ("ODE")] **will contact your facility to make arrangements for return of your URF-V2/V2R Uretero-reno videoscope(s) for the device exchange.** You can continue to use the URF-V2/V2R Uretero-reno videoscope 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-V2/V2R Uretero-reno videoscope(s). **[Name of your company] requests you to take the following immediate action:**

1. Inspect your inventory and identify any URF-V2/V2R models.
2. **[Name of your company; e.g. Olympus Germany. ("ODE")] will contact your facility within the next ten months to make arrangements for return of your URF-V2/V2R Uretero-reno videoscope(s) for the device exchange.** You will be provided instructions on returning the URF-V2/V2R for this exchange. You do not need to proactively contact Olympus and can continue to use your existing URF-V2/V2R Uretero videoscope(s).
3. 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.
4. Please indicate on the enclosed Reply Form that you have received this notification. Additionally please fill the number of the affected URF-V2/V2R 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,