Date: December XX, 2016

URGENT: URGENT FIELD SAFETY NOTICE

Attention: Operating Room Manager
Risk Management Department

RE: OLYMPUS Uretero-reno Endoscopes
Models: URF-V2, URF-V2R, URF-P6, URF-P6R
Serial numbers: all serial numbers

Dear Health Care Practitioner:

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, URF-P6 and URF-P6R Uretero-reno fiberscopes and our records indicate that your facility has purchased one or more of these products. The URF-V2, URF-V2R and the URF-P6, URF-P6R endoscopes are intended for use in endoscopic diagnosis and treatment within the ureter and kidney. The URF-P6 and P6R endoscopes are also intended for use in endoscopic diagnosis and treatment within the biliary tract (common bile duct and hepatic duct).

Olympus has initiated this corrective action following investigation of five adverse events on the **URF-V2 and URF-V2R** regarding the breakage of the endoscope's insertion tube bending section during surgical procedures. To date, these adverse events are associated in two cases with tissue trauma, one case of perforation, and two cases of insertion tubes which were stuck inside the patient and had to be surgically removed. Olympus is writing to advise you on this matter and to recommend action.

Regarding the **URF-P6, URF-P6R** Olympus has received complaints regarding breaks of the bending tube – none of them resulted in an adverse event.

In an effort to mitigate a potential risk to patient or user health, Olympus is undertaking this action to notify users of these adverse events and complaints as well as the need for careful inspection of the endoscopes prior to use in accordance with the instructions provided below.

Olympus requests you to report any patient injuries associated with Olympus endoscopes. Contact [the OLYMPUS Customer Care Center / the OLYMPUS Service Center / your local OLYMPUS representative] at [telephone number].

Action Steps:
Olympus requires that you to 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-V2, URF-V2R, URF-P6 and URF-P6R prior to patient use according to the enclosed Instructions for Safe Use. The URF-V2, URF-V2R and URF-P6, URF-P6R **Operation Manuals** contain 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-V2, URF-V2R, URF-P6 and URF-P6R **Operation Manuals** contain 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 form that you have received this Safety Notice.
4. Fax the completed form to xxx-xxx-xxxx.

OLYMPUS regrets any inconvenience from this action and fully appreciates your prompt cooperation in addressing this situation. Please do not hesitate to contact us directly at xxx-xxx-xxxx or at xxxx@olympus.com if you have any questions on this matter.

Regards,

Name
Division