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Your Vision, Our Future

Reference: 2018-001M

February 20, 2018

URGENT FIELD SAFETY NOTICE

RECALL OF OLYMPUS URF-P6/P6R AND URF-V2/V2R URETERO-RENO ENDOSCOPES

Dear Sir/Madam,

OLYMPUS is implementing a Recall of all URF-P6/P6R and URF-V2/V2R Uretero-reno Endoscopes due to the bending mechanism complaints. This Recall is a follow-up to the *Important Quality Notice (Ref: 2016-006M)* issued to your facility on December 23, 2016. The affected models are:

- URF-P6 Uretero-reno Fiberscope
- URF-P6R Uretero-reno Fiberscope
- URF-V2 Uretero-reno Videoscope
- URF-V2R Uretero-reno Videoscope

All serial numbers are affected.

The URF-P6/P6R Uretero-reno Fiberscopes ("**URF-P6/P6R**") and URF-V2/V2R Uretero-reno Videoscopes ("**URF-V2/V2R**") are intended for endoscopic diagnosis and treatment within the ureter and kidney through a percutaneous route and transurethrally.

In December 2016, OLYMPUS initiated a Field Safety Corrective Action (FSCA) to notify customers of potential for breakage of the endoscope's insertion tube and the need for careful inspection of the URF-P6/P6R and URF-V2/V2R prior to use, as per the Instructions for Safe Use. The FSCA arise due to complaints received on URF-V2/V2R associated with tissue trauma, ureter perforation and insertion tube which was stuck inside patient but surgically removed. Subsequently, investigation found the breakage within the endoscope's insertion tube contributed to these adverse event. There were complaints on URF-P6/P6R insertion tubes and breaks of insertion tube bending section, but these complaints have not resulted in any known adverse events. As URF-P6/P6R has a similar structure to URF-V2/V2R, OLYMPUS decided to take the same action for the URF-P6/P6R as the URF-V2/V2R.

In an effort to mitigate the occurrence of adverse events, OLYMPUS decided to replace the existing URF-P6/P6R and URF-V2/V2R with a modified version. The modified URF-P6/P6R and URF-V2/V2R are manufactured with a new design that has improved durability at the bending section. Modified URF-P6/P6R and URF-V2/V2R can be identified by serial number which has "3" as the third digit. To achieve this, OLYMPUS will remove all existing URF-P6/P6R and URF-V2/V2R in the market and provide device replacement for all users.

OLYMPUS SINGAPORE PTE LTD
Business Regn No. 198900566E
491B River Valley Road #12-01/04 Valley Point Office Tower Singapore 248373 Tel: (65) 6834 0010 Fax: (65) 6834 2438
www.olympus.com.sg

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Actions to be taken by end user

Our records indicate your facility has purchased the URF-P6/P6R Uretero-reno Fiberscope(s) and URF-V2/V2R Uretero-reno Videoscopes from OLYMPUS.

OLYMPUS requests you to take the following actions immediately:

1. Inspect your inventory and identify all affected URF-P6/P6R and URF-V2/V2R models.

2. Your local Olympus representative will contact your facility to arrange for return and replacement of the affected URF-P6/P6R and/or URF-V2/V2R.

3. Please acknowledge on the enclosed "Response Form" that you have received this Field Safety Notice ("FSN") and include the quantity of affected devices you have identified in your inventory.

4. Email the completed "Response Form" to the Regulatory Affairs Department at mes-ra.osp@olympus-ap.com, or you may return the completed form to your local Olympus representative.

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 us for additional information.

Contact information

Olympus Singapore Pte. Ltd.
Regulatory Affairs Department
Email: mes-ra.osp@olympus-ap.com
Tel: (+65) 6833 4214
Fax: (+65) 6834 2438

Sincerely,

[redacted]

Loh E Thel
Deputy Division Manager
Medical Systems Business Division
Olympus Singapore Pte. Ltd.

cc: Chairman Medical Board and relevant Head of Departments