



December 12, 2011

URGENT – DEVICE CORRECTION

Re: Irrigation tubing for Olympus Flushing Pump, Model OFP
Part number: 7501669

Dear Health Care Practitioner:

Olympus America Inc. ('OAI') is initiating a corrective action to address complaints associated with water leaking from the irrigation tubing used with the Olympus flushing pump. The Olympus OFP Flushing Pump is a peristaltic flushing pump intended for use with Olympus gastrointestinal videoscopes having an auxiliary water inlet as part of an Olympus endoscopic imaging system to facilitate washing of gastric and colonic mucosa with water to remove organic matter, enabling improved visualization, diagnosis and therapy during endoscopic procedures.

Olympus has initiated this corrective action following investigation of customer complaints associated with water leaking from the irrigation tubing used on the OFP pump. In one complaint, a hospital staff member slipped on water that had pooled on the floor from the leaking tubing.

Our records indicate that your facility has purchased irrigation tubing within the past two years for the OFP pump. Olympus is requiring that you take the following action:

1. Olympus is discontinuing the current version of irrigation tubing. Any current irrigation tubing in your inventory can be used with the OFP pump, however, Olympus requests that you inspect the tubing installed on the OFP pump for any signs of water leakage. If you discover any signs of water leakage from the tubing, discontinue use of the tubing and replace with a new irrigation tube.
2. Please indicate on the enclosed questionnaire any irrigation tubing found to be leaking when installed on the OFP pump. Olympus will replace your leaking irrigation tubing.

Olympus has redesigned the irrigation tubing to prevent water leakage. The new, revised irrigation tubing is provided sterile, ready for use and the need for a filter is no longer required. The new irrigation tubing is designed for use with both the OFP and OFP-2 flushing pumps, and it can be ordered in packs of 10 units or 50 units. Item number K10001147 is for a pack of fifty irrigation tubes and item number K10016135 is for a pack of ten irrigation tubes. A new cap for the sterile water bottle is required in order to use the new irrigation tubing when used with the OFP. Your sales representative will provide sterile water bottle caps at no charge.

OLYMPUS AMERICA INC.

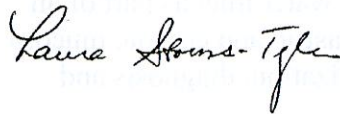
3500 CORPORATE PARKWAY, P.O. BOX 610, CENTER VALLEY, PA 18034-0610
TELEPHONE (484) 896-5000

If you do not wish to use your current inventory of irrigation tubing and would like a replacement or credit, please call the Olympus Customer Care Center at 1-800-848-9024, option 2.

Please indicate on the enclosed form that you have received this information. Fax this completed questionnaire to Cherene Mastroianni at facsimile number (484) 896-7128.

Olympus regrets any inconvenience from this recall and fully appreciates your prompt cooperation in addressing this situation. Please do not hesitate to contact me directly at (484) 896-5688 or by e-mail at laura.storms-tyler@olympus.com for any additional information on this matter.

Sincerely,



Laura Storms-Tyler
Olympus America Inc.
V.P., Regulatory/Clinical Affairs & Quality Assurance



OLYMPUS OFP Irrigation Tubing Corrective Action

Affected Part number: 7501669

I have received the recall information on the Olympus OFP irrigation tubing referenced above and understand that I need to inspect tubing installed on the OFP pump for any signs of water leakage.

I have:

_____ have checked my inventory and no longer have this product

_____ have checked my inventory and discarded the following number of tubing due to water leakage: _____

Institution: _____

Address: _____

City: _____ State: _____ Postal Code: _____

Name: _____

Phone number: _____

Fax completed questionnaire to Olympus at 484-896-7128

OLYMPUS AMERICA INC.

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