OLYMPUS

September 20, 2024

URGENT: MEDICAL DEVICE CORRECTION

Olympus OFP-2 Flushing Pump

Product Name: OFP-2 Flushing Pump

Catalog number	Serial Number Range	UDI-DI
OFP-2 (K10001141)	22324536 to 22414624 Purchased prior to April 1, 2024	15019778003191

Attention: Operating Room, Biomedical Department

Dear Healthcare Provider:

Olympus is writing to inform you of a Field Safety Corrective Action pertaining to the Olympus OFP-2 Flushing Pump ("OFP-2"). The OFP-2 is a peristaltic pump intended to supply fluid to compatible Olympus endoscopes or endotherapy devices for irrigation of the gastric and colonic mucosa during endoscopic or endotherapeutic procedures, allowing improved visualization, diagnosis, and treatment. The pump can also assist in the use of transendoscopic ultrasound probes by rapidly filling the organ to be examined.

Reason for Action:

During product testing, Olympus identified an intermittent loss of function of the OFP-2 Flushing Pump caused by an internal component connection failure. In the event that the connection failure occurs, the OFP-2 device will return to or remain in the "Off" condition and the operator will not be able to use the flushing function. Through its investigation, Olympus determined that this issue resulted from an alternate tool being used during the manufacturing of one (1) lot of the subject component. Olympus has received three (3) complaints that are potentially applicable to this issue. No adverse events have been reported.

To address this issue, Olympus Repair Facilities will perform an inspection of your OFP-2 device(s), and repair if necessary.

Risk to Health:

In the event there is an intermittent loss of function of the OFP-2 Flushing Pump this would not impede the physician's ability to complete the procedure; however, if identified during preparation of the device this can lead to a delay in initiating the procedure, or if noticed during use it can prolong the procedure to either replace the device and/or the user can elect to complete the procedure with alternative methods of endoscopic irrigation available in the procedural room setting.

Actions Required:

Our records indicate that your facility has purchased one or more of the affected products. The range of affected serial numbers is included at the top of this letter. The serial number is on a label affixed to the back of the OFP-2 pump.

An Olympus representative will create a Return Material Authorization for the return of your device to Olympus for an inspection. You may continue to use your OFP-2 pump until an Olympus representative performs the inspection. If the OFP-2 fails the inspection, the OFP-2 will require repair.

Additionally, Olympus requires you to take the following actions:

1. Carefully read the content of this notification.
2. Olympus requests that you acknowledge receipt of this letter. Access the Olympus recall portal to indicate that you have received this notification.
    a. Go to https://olympusamerica.com/recall
    b. Enter the recall number "0455"
    c. Complete the form as instructed.
3. If you have further distributed this product, identify your customers, and forward them this notification.
4. Beginning November 2024, please contact Olympus Customer Service at 1-800-848-9024, option 3, to request an "Air Switch Assembly Inspection". Olympus will arrange for the return of your device to our Olympus Repair Center at a mutually convenient time. The Olympus representative's record of repair will also serve as the completion record of this action for your facility.

Olympus requests that you report any complaints, including loss of function of the OFP-2 pump, or any associated injuries to the Technical Assistance Center (TAC) at 1-800-848-9024, option 1, and the FDA. Adverse events experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact me directly by phone at (647) 999-3203 or by e-mail at Cynthia.Ow@Olympus.com.

Sincerely,

Cynthia Ow

Cynthia Ow
FCA Regional Lead, Americas