September 13, 2024

URGENT: MEDICAL DEVICE REMOVAL
OLYMPUS EZDilate Wire Guided Balloon

Product Name	Model/Catalog Number	Lot Number	UDI PI
EZDilate Single-Use Wire Guided Esophageal/ Pyloric / Biliary Balloon Dilators, 8.5 mm-9.5 mm-10.5 mm	*BD-410X-1055*	*408987*	*821925033238*

Attention: Endoscopy Department, Risk Management Department

Dear Healthcare Professional /Provider:

Olympus is writing to inform you of a Medical Device Removal pertaining to the Olympus EZDilate Wire Guided Balloon model BD-410X-1055, Lot Number 408987. The EZDilate Wired Guided Balloons are indicated for use in adult and adolescent (>12 years) populations to endoscopically dilate strictures of the alimentary tract. It is also indicated in adults for endoscopic dilatation of the Sphincter of Oddi with or without prior sphincterotomies.

Reason for Action:
Olympus received 4 complaints between March 2024 and June 2024 from customers indicating the balloon was packaged with the incorrect Glo Cath Label applied to the Balloon Dilation Catheter for the diameter sizes. The incorrect label states 11 mm, 12 mm, 13 mm however the balloon is 8.5mm, 9.5mm and 10.5 mm. See image below. All other labeling is correct for the balloon, including the Shelf Box with Front Box Label and Circular Star Label and the balloon Pouch.

Shelf Box with Front Box Label | Pouch Label | Balloon Dilation Catheter with Incorrect Label

OLYMPUS CORPORATION OF THE AMERICAS
3500 CORPORATE PARKWAY, CENTER VALLEY, PA 18034
TELEPHONE (484) 896-5000

Risk to Health:
Four (4) complaints about the BD-410X-1055 were received with no identified serious injuries. The consequences of an incorrect Glo Cath label could include risk of prolonging the procedure to replace the device, cancellation if no alternative device replacement is available, and a decrease in the patient's therapeutic response if the balloon does not inflate to its intended diameter.

Actions Required:
Our records indicate that your facility has purchased one or more of the affected products. Therefore, Olympus requires you to take the following actions:

1. Carefully read the content of this notification.
2. Examine your inventory and identify the above-listed device with the affected batch number.
3. Please contact Customer Service at 1-800-848-9024, option 2, to obtain a Return Material Authorization. Olympus will arrange for the return of your device to Olympus. When it is received, you will receive a credit for your affected device(s).
4. If you have further distributed this product, identify your customers, and forward them this notification.
5. 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 "**0453**"
    c) Complete the form as instructed.

Olympus requests that you report any complaints, including any incorrect labeling, to the Olympus Technical Assistance Center (TAC) at 1-800-848-9024 (option 1). 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 by e-mail at Cynthia.Ow@Olympus.com or by phone at (647) 999-3203.

Sincerely,

Cynthia Ow

Cynthia Ow
Field Corrective Action Regional Lead, Americas