October 11, 2024

URGENT: MEDICAL DEVICE CORRECTION

Olympus Laser Cystoscope

Product Name: Cystoscope Outer sheath, 22.5 Fr.

Catalog number	Serial Number Range	UDI-DI
WA22810A	All	04042761051729

Attention: Operating Room Director, Urology Department, and Risk Management

Dear Healthcare Provider:

Olympus is writing to inform you of a Field Safety Corrective Action pertaining to the above referenced Cystoscope Outer sheath which is an outer sheath used for endoscopic diagnosis and treatment in urological applications.

Reason for Action:

Olympus has received six complaints about a damaged tip during use of a laser probe. Olympus has not received any reported injuries related to this matter. As a result of this complaint investigation, Olympus is removing the statement of compatibility with a GreenLight Laser for BPH therapy from the Instruction for Use (IFU) until Olympus can conduct additional testing. Due to this situation, customers should not use this product in conjunction with a GreenLight Laser for BPH therapy until further notice from Olympus.

Risk to Health:

Use of the Cystoscope Outer Sheath with a GreenLight Laser for BPH therapy may result in damage and/or overheating to the tip of the sheath. Damage to the sheath tip, if recognized during use, could potentially cause rough or sharp edges on the device, requiring the device to be replaced before or during the procedure. In rare cases, unrecognized sheath damage could result in tissue injury or parts of the sheath breaking off into patient, with a requirement for removal. Overheating of the distal tip of the sheath may, in rare cases, cause stenosis.

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.
3. You should not use the Cystoscope Outer sheath, 22.5 French with a GreenLight Laser for BPH therapy until further notice from Olympus. Add a copy of this letter to any on-hand copies of the Instructions for Use.
4. Olympus requests that you acknowledge receipt of this letter. Acknowledge receipt of this letter through the Olympus web portal:

a. Go to https://olympusamerica.com/recall
b. Enter the recall number "0460"
c. Complete the form as instructed.

5. If you have further distributed this product, identify your customers, and forward them this notification.

Olympus requests that you report any complaints, including the device breaking off into the patient, 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 by phone at (647) 999-3203 from Monday through Friday, 9 am to 5 pm EDT, or by e-mail at Cynthia.Ow@olympus.com.

Sincerely,

Cynthia Ow

Cynthia Ow
Field Corrective Actions Lead, Americas