

URGENT: MEDICAL DEVICE REMOVAL
Olympus Laser Cystoscope Outer sheath

Product Name: Cystoscope Outer sheath, 22.5 Fr.

| Catalog number | Serial Number Range | UDI-DI |
|----------------|---------------------|----------------|
| WA22810A | All | 04042761051729 |

Date: 15-Jan-2026

Attention: Operating Room Director, Urology, and Risk Management

Dear Healthcare Provider:

In August 2024, Olympus issued a field safety notice (FSN) in relation to the Cystoscope Outer sheath, 22.5 Fr. The FSN instructed users that the Cystoscope Outer sheath should not be used with a GreenLight Laser for BPH therapy until further notice from Olympus. Olympus is now writing to inform you of a voluntary product removal field safety corrective action for the above referenced Cystoscope Outer sheath. The intended use of the Cystoscope Outer sheath is to be used for endoscopic diagnosis and treatment in urological applications.

Immediately cease usage of any Cystoscope Outer sheath, 22.5 Fr in your inventory.

Reason for Action:

Olympus has received eight complaints globally about a Cystoscope Outer sheath damaged tip during use of a laser probe. Olympus has not received any reported injuries related to this matter. Though the risks associated with the use of a Cystoscope with the laser probe have not changed since the previous FSN, we conducted additional testing, which indicated further regulatory actions would be required in order to state compatibility of the cystoscopy sheath with GreenLight laser fibers. Accordingly, we have made the decision to discontinue the product and remove the device from the market.

Risk to Health:

The risks associated with the use of a Cystoscope sheath with the laser probe have not changed since the previous FSN. Use of the Cystoscope Outer sheath with any type of GreenLight Laser for BPH therapy may result in damage and/or overheating to the tip of the sheath. Damage to the sheath tip could potentially cause rough or sharp edges on the device, requiring the device to be replaced before use or during the procedure when recognized. In rare cases, unrecognized sheath damage could result in tissue injury or parts of the sheath breaking off in the patient, requiring removal. Overheating of the distal tip of the sheath may, in rare cases, cause stenosis.

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

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. Examine your inventory and quarantine any identified devices immediately.
2. **Immediately cease usage of any affected products in your inventory.**
3. Olympus requests that you acknowledge receipt of this letter through our recall web portal:
 - a. Go to <https://olympusamerica.com/recall>
 - b. Enter the recall number: "0488"
 - c. Complete the form as instructed.
4. 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. Olympus will issue a credit to your facility upon receipt of your WA22810A outer sheath.
5. If you have further distributed this product, please forward this notification to other users.

Olympus requests that you report any complaints, including 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. If you require additional information, please do not hesitate to contact me at Cynthia.Ow@olympus.com or by phone at (647) 999-3203.

Sincerely,

Cynthia Ow

Cynthia Ow
Sr. Manager
Field Corrective Action, Americas