URGENT FIELD SAFETY NOTICE

Olympus Laser Cystoscope Outer sheath

Product Name: Cystoscope Outer sheath, 22.5 Fr.

Catalog number	Serial Number Range	UDI-DI
WA22810A	All	04042761051729

Date: *DD*-Jan-2026

Attention: Operating Room, Biomedical Department

Dear Healthcare Provider:

Olympus is 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.

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. As a result of this complaint investigation, Olympus conducted additional testing to verify the statement of compatibility with a GreenLight Laser for BPH therapy in the Instruction for Use (IFU). As further regulatory actions would be required in order to state compatibility of the cystoscopy sheath with GreenLight laser fibers, we have made the decision to discontinue the product and remove the device from the market.

Risk to Health:

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.

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 *[local facility method/contact].*
4. Please contact Customer Service at XXXXX to obtain a Return Material Authorization. Olympus will arrange for the return of your device to Olympus.

5. Please forward this notice to other users who may have the affected products if you have further distributed it.

[If applicable:] [competent authority] is aware of the actions described in this letter.

Olympus requests that you report any complaints, including loss of function of the xxxx, or any associated injuries to *[local facility complaint reporting contact].* Adverse events experienced with the use of this product may also be reported *[local competent authority]* by *[method].*

Olympus fully appreciates your prompt cooperation. If you require additional information, please do not hesitate to contact *[me directly at XXXX@olympus.com/ Olympus directly at (XXX) XXX-XXXX from Monday through Friday or by e-mail at XXX].*

Sincerely,

Name
Olympus title