



Date: April 20, 2022

**URGENT: MEDICAL DEVICE CORRECTION**  
**OLYMPUS CYSTONEPHROFIBERSCOPE and**  
**URETERO-RENO FLEXIBLE VIDEOSCOPE**  
**Model: CYF-5, URF-P6, URF-P6R**  
**Serial Number/UDI: See Attachment**

Dear Healthcare Practitioner:

Olympus Medical Systems Corporation (“Olympus”) is initiating a corrective action in the U.S. for *OLYMPUS CYSTONEPHROFIBERSCOPE and URETERO-RENO FLEXIBLE VIDEOSCOPE* with serial numbers in the attachment.

The CYF-5 cystonephrofiberscope is designed to be used with an Olympus light source, documentation equipment, display monitor, endo-therapy accessories and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra and kidney.

The URF-P6 and URF-P6R uretero-reno flexible videoscopes are designed to be used with an Olympus light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the ureter, kidney, and biliary tract (common bile duct and hepatic duct).

**Corrective Action**

Olympus has initiated this corrective action following the discovery and investigation regarding an incorrect adhesive used during your last through our Olympus America Service Center. The incorrect adhesive was used to secure the diopter ring and nameplate ring. Although the composition and tensile strength of the adhesives are similar in property, longer term effects of non-standard adhesives are unknown.

The diopter ring is used to focus the field of view of the eyepiece, which is secured by a screw, the adhesive subject to this corrective action and then an additional adhesive overlay. An improperly connected diopter ring may result in the loss of adjustment function leading to a blurred field of vision. Such situation could possibly lead to an unintentional contact with the patient’s body and in rare cases perforation in the urinary tract/renal pelvis.

The nameplate ring does not have any function and is cosmetic to display the Olympus name.

Olympus has not received reports or complaints associated with this matter. Olympus requests that you report complaints and adverse events to Olympus and to the FDA through a MedWatch report. Call our Technical Assistance Center (TAC) at 1-800-848-9024, option 1 to report complaints.

**Accordingly, Olympus is initiating this action to repair your device.**

## **Action steps to be taken by the end user:**

Our records indicate that your facility has received the referenced device from our Olympus America Service Center. Olympus requires **the following actions:**

1. Identify the affected model and serial number in the subject of this letter. The serial number can be found on the device as illustrated in the following picture.



**Location of serial number for  
model CYF-5**



**Location of serial number for  
models URF-P6, URF-P6R**

2. An Olympus representative will contact you to make arrangements for the return of your affected device. Olympus will repair your unit free of charge. In the meantime, follow the instruction manual for inspection of the device before use. Should any irregularities be identified, including a loose parts, do not use the device and contact Olympus for repair.
3. Olympus will arrange for a service loaner in an effort to not disrupt clinical care.

Olympus regrets any inconvenience from this corrective action and fully appreciates your prompt cooperation in addressing this situation. Please do not hesitate to contact me directly at 647-999-3203 or at [Cynthia.Ow@Olympus.com](mailto:Cynthia.Ow@Olympus.com) for any additional information or support concerning this matter.

Sincerely,

Cynthia Ow  
Field Corrective Actions Lead, Americas

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**Attachment 1 – List of Affected Models and Serial Numbers**

	<b>Model</b>	<b>Name</b>	<b>Serial Number</b>	<b>UDI</b>
1	CYF-5	Cysto Nephrofiberscope	2355088	04953170339417
2	CYF-5	Cysto Nephrofiberscope	2456630	04953170339417
3	CYF-5	Cysto Nephrofiberscope	2557155	04953170339417
4	CYF-5	Cysto Nephrofiberscope	2769732	04953170339417
5	CYF-5	Cysto Nephrofiberscope	2972060	04953170339417
6	CYF-5	Cysto Nephrofiberscope	7171632	04953170339417
7	CYF-5	Cysto Nephrofiberscope	W501648A	04953170339417
8	URF-P6	Uretero-Reno Flexible Videoscope	2836210	04953170340802
9	URF-P6	Uretero-Reno Flexible Videoscope	2834747I	04953170340802
10	URF-P6R	Uretero-Reno Flexible Videoscope	2835978	04953170340833
11	URF-P6R	Uretero-Reno Flexible Videoscope	2836299	04953170340833
12	URF-P6R	Uretero-Reno Flexible Videoscope	2837272	04953170340833
13	URF-P6R	Uretero-Reno Flexible Videoscope	2836209F	04953170340833