

## URGENT: FIELD SAFETY NOTICE

### MacroLux CoralView Single-use Digital Flexible Ureteroscopes, and MacroLux BubbleView Single-use Digital Flexible Cystoscopes

**Model Number:** See attachment

**Lot Number/UDI-DI:** See attachment

Date: January 28, 2026

Attention: Urology Department, Risk Management

Dear Customer/Healthcare Professional,

MacroLux Medical Technology Co., Ltd. has informed Olympus of an Advisory Notice requiring your attention. This action pertains to specific lot numbers of the CoralView Single-use Digital Flexible Ureteroscopes and BubbleView Single-use Digital Flexible Cystoscopes listed in the attachment. Devices received after December 12<sup>th</sup>, 2025, are not affected by this issue.

Please refer to the attached Advisory Notice from the manufacturer, MacroLux, for information on the issue, the reason for action, and the risks.

#### **Reason for Action:**

Packaging of affected devices may have missing or incorrect labels (Refer to Section 4. Problem Statement in the enclosed MacroLux Advisory Notice).

#### **Actions Required:**

Our records indicate that your facility has received one or more affected units. Olympus requests you to take the following actions:

1. Examine your inventory and quarantine any affected devices with the lot number(s) listed in the attachment shipped before December 12<sup>th</sup>, 2025.
2. Carefully read the content of the attached Advisory Notice from MacroLux.
3. Check for the labeling non-conformances listed, as follows:
  - a. Refer to **Section 6. Recommended Corrective Actions** in the Advisory Notice to determine if you should dispose of your affected products.
  - b. Review examples shown in **Appendix 2** of the Advisory Notice.
4. Olympus requests that you acknowledge receipt of this letter even if you no longer have the device.
  - a. Go to <https://olympusamerica.com/recall>
  - b. Enter the file reference number "0491"
  - c. Complete the form as instructed.
5. If you have further distributed it, forward this notice to other users who may have the affected device.

Olympus requests that you report any complaints, including mislabeling packaging, to our Technical Assistance Center (TAC) at 1- 800-848-9024, option 1, and the FDA. Adverse events experienced with the use of this

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

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 or by email at Cynthia.Ow@Olympus.com.

Sincerely,

*Cynthia Ow*

Cynthia Ow  
Sr. Manager  
Field Corrective Action, Americas

## **URGENT: FIELD SAFETY NOTICE**

### **MacroLux CoralView Single-use Digital Flexible Ureteroscope, and BubbleView Single-use Digital Flexible Cystoscope**

#### **Attachment – Affected Model, Lots Distributed in the United States**

Note: Devices shipped after December 12<sup>th</sup>, 2025, are not affected by this action

<b>Product Name</b>	<b>Model</b>	<b>Lot number</b>
BubbleView	C50-CR	125080062
BubbleView	C50-C	A25080016
BubbleView	C50-CR	125080062
BubbleView	C50-C	A25080020
BubbleView	C50-C	A25090002
BubbleView	C50-C	125080139
BubbleView	C50-CR	125090164
BubbleView	C50-CR	125090015
BubbleView	C50-CR	125080062
BubbleView	C50-C	A25080016
BubbleView	C50-C	A25080020
BubbleView	C50-CR	125090015
BubbleView	C50-CR	125090164
CoralView	U10-BR	125085083
CoralView	U20-BR	125085068
CoralView	U10-B	125085082
CoralView	U20-B	125085067
CoralView	U10-B	125085082
CoralView	U10-BR	125085083
CoralView	U20-B	125085067
CoralView	U20-BR	125085068
CoralView	U20-B	125095126
CoralView	U20-B	125085067
CoralView	U20-B	125095051
CoralView	U20-BR	125085068
CoralView	U20-BR	125095001
CoralView	U20-BR	125095150

## Advisory Notice

**MacroLux Medical Technology Co., Ltd.**

**301, Building 3, NamTai Inno Park In Guang Ming Avenue, Guangming, 518107 Shenzhen, PEOPLE'S REPUBLIC OF CHINA**

Issue Date: 2025/12/10

### 1. Purpose and Scope

This advisory notice is to inform customers of potential non-conformity related to CoralView and BubbleView, and to provide necessary actions to ensure device safety and regulatory compliance.

**This advisory notice applies to devices already distributed in United States (U.S.).**

### 2. Device Description

The CoralView Single-use Digital Flexible Ureteroscope is intended to be used to visualize organs, cavities and canals in the urinary tract (urethra, bladder, ureter, calyces and renal papillae) via transurethral access routes. It can also be used in conjunction with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract.

The BubbleView Single-Use Digital Flexible Cystoscope is a sterile, single-use, flexible endoscope intended to be used for endoscopic access to and examination of the lower urinary tract. The BubbleView is intended to provide visualization via ViewHub video processor and can be used with endoscopic accessories.

### 3. Scope of Affected Devices

See Appendix 1 for details.

### 4. Problem Statement

We state that the above affected devices may have missing or incorrect labels and IFU, with details of the specific non-conformities provided in Appendix 2. We also state that devices shipped after November 28th will not be subject to the above issues.

### 5. Risk Assessment

Non-conformances/ Failure Modes	Hazardous situation and Harm	Risk estimation	Risk evaluation
Missing importer label on various levels of packaging	The importer label is a compliance requirement that does not apply to the United States; therefore, this failure mode will not result in any hazardous situations or cause harm.	Severity: S1(Negligible) Probability: P1(Remote)	ACC
Missing or incorrect product labels on the secondary packaging or shipping packaging (outer carton)	Insufficient instructional information, improper storage of the device, device damage, user use of damaged devices, and patient harm	Severity: S1(Negligible) Probability: P1(Remote)	ACC
Missing product labels on primary packaging (Sterile Packaging)	Lack of clear device identification, unintended use of the device, and patient harm	Severity: S1(Negligible) Probability: P3(Occasional)	ACC
Missing CI label on various levels of packaging	The purpose of the CI label is to identify the sterilization status of the device and support on-site management prior to device shipment. Based on relevant data, we confirm that all affected devices are in a sterilized state; therefore, this will not result in any hazardous situations or cause harm.	Severity: S1(Negligible) Probability: P1(Remote)	ACC
Missing all IFUs in the secondary packaging	Lack of necessary usage instructions and warning information for the device, misuse of the device, and patient harm	Severity: S1(Negligible) Probability: P3(Occasional)	ACC
Missing one IFU or Duplicate IFU present in the secondary packaging	Missing one IFU or inclusion of an extra copy of the correct IFU will not result in any hazardous situations or cause harm.	Severity: S1(Negligible) Probability:	ACC

		PI(Remote)	
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Note: The risk assessment is conducted in accordance with KF-1101-02-010 Version 2.0 Risk Management Plan and KF-1104-02-002 Version 3.0 Risk Management Plan.

**6. Recommended Corrective Actions**

We recommend that users check for the non-conformances stated in this notice when retrieving devices from the packaging of the above affected devices. Based on the risk assessment, the risks associated with these non-conformances are acceptable for some units; however, considering various factors, we recommend that users adopt the following response measures for non-conforming devices:

<b>Non-conformances/ Failure Modes</b>	<b>Response measures for non-conforming devices</b>
Missing importer label on various levels of packaging	Retain and Use.
Missing or incorrect product labels on the secondary packaging or shipping packaging (outer carton)	Retain and Use.
Missing product labels on primary packaging (Sterile Packaging)	Dispose of the device in accordance with local policies
Missing CI label on various levels of packaging	The CI label is absent only from the shipping packaging (outer carton): Retain and Use. The CI label is absent from the primary packaging: Dispose of the device in accordance with local policies
Missing all IFUs in the secondary packaging	Dispose of the devices in the entire shipping packaging (outer carton) in accordance with local policies
Duplicate IFU present in the secondary packaging	Retain and Use.

**7. Our Support Information**


You may seek assistance by contacting your distributor or MacroLux sales representative, or provide feedback via the following email.

Email: [yelinbin@microlite.cn](mailto:yelinbin@microlite.cn)

**8. Regulatory Compliance Statement**

This advisory notice complies with ISO 13485:2016 and the medical device regulatory requirements of the applicable jurisdictions, fulfilling the manufacturer’s responsibility for ongoing risk control of marketed devices.

**Issued by:**

Signature: 

Name: Linb

Position: Management Representative

City: Shenzhen

Date: 2025-12-10

Appendix 1 Scope of Affected Devices

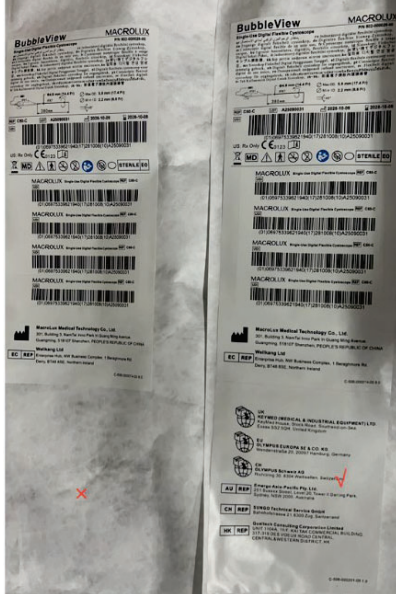
Trade Name	FDA Device Class	FDA Product Code	FDA Premarket Submission Number	Catalog Number	Model number	Batch number
BubbleView	2	FAJ	K240283	802-000027-00	C50-CR	125080062
BubbleView	2	FAJ	K240283	802-000026-00	C50-C	A25080016
BubbleView	2	FAJ	K240283	802-000027-00	C50-CR	125080062
BubbleView	2	FAJ	K240283	802-000026-00	C50-C	A25080020
BubbleView	2	FAJ	K240283	802-000026-00	C50-C	A25090002
BubbleView	2	FAJ	K240283	802-000026-00	C50-C	125080139
BubbleView	2	FAJ	K240283	802-000027-00	C50-CR	125090164
BubbleView	2	FAJ	K240283	802-000027-00	C50-CR	125090015
BubbleView	2	FAJ	K240283	802-000027-00	C50-CR	125080062
BubbleView	2	FAJ	K240283	802-000026-00	C50-C	A25080016
BubbleView	2	FAJ	K240283	802-000026-00	C50-C	A25080020
BubbleView	2	FAJ	K240283	802-000027-00	C50-CR	125090015
BubbleView	2	FAJ	K240283	802-000027-00	C50-CR	125090164
CoralView	2	FGB	K231774	802-000032-00	U10-BR	125085083
CoralView	2	FGB	K231774	802-000035-00	U20-BR	125085068
CoralView	2	FGB	K231774	802-000031-00	U10-B	125085082
CoralView	2	FGB	K231774	802-000034-00	U20-B	125085067
CoralView	2	FGB	K231774	802-000031-00	U10-B	125085082
CoralView	2	FGB	K231774	802-000032-00	U10-BR	125085083
CoralView	2	FGB	K231774	802-000034-00	U20-B	125085067
CoralView	2	FGB	K231774	802-000035-00	U20-BR	125085068
CoralView	2	FGB	K231774	802-000034-00	U20-B	125095126
CoralView	2	FGB	K231774	802-000034-00	U20-B	125085067
CoralView	2	FGB	K231774	802-000034-00	U20-B	125095051
CoralView	2	FGB	K231774	802-000035-00	U20-BR	125085068
CoralView	2	FGB	K231774	802-000035-00	U20-BR	125095001
CoralView	2	FGB	K231774	802-000035-00	U20-BR	125095150

Appendix 2 Specific non-conformances

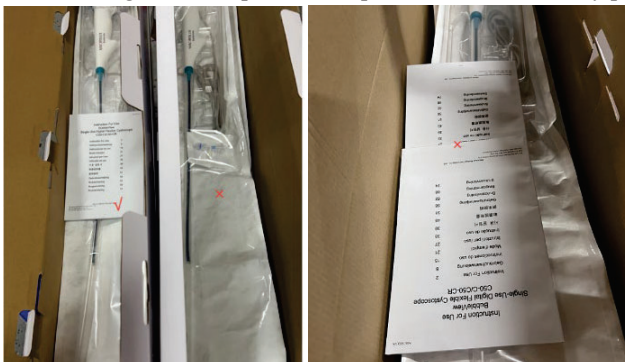
- Missing importer label on Shipping packaging (outer carton)



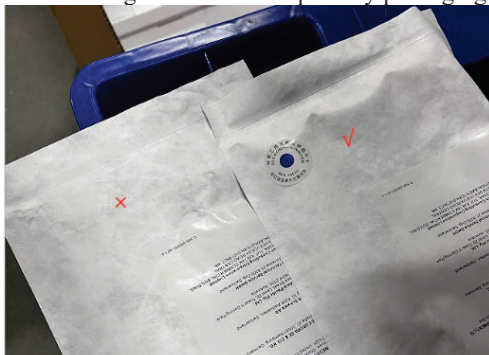
- Missing importer label on primary packaging (Sterile Packaging)



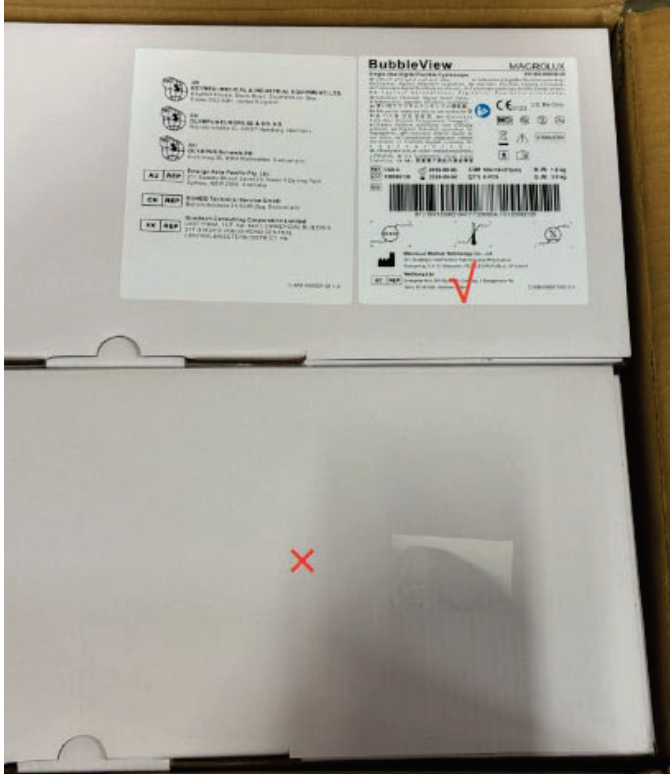
- Missing IFU or duplicate IFU present in the secondary packaging



- Missing the CI label on primary packaging (Sterile Packaging)



- Missing Product label and importer label on secondary packaging



- Carton level box was incorrectly labeled with the shipper level

