Reference: 2027-X001M

10 August 2026

URGENT: MEDICAL DEVICE REMOVAL

Product: OLYMPUS Hemostasis Devices

Product Name	Model Number	Lot Numbers
BiCOAG Hemostasis Probe	CD-B610LA CD-B612LA CD-B620LA CD-B622LA	All (within expiry date)

Attention: **Operating Room / Endoscopy and Risk Management Departments**

Dear Healthcare Professional:

Olympus is writing to inform you of a Medical Device Removal Action affecting BiCOAG Hemostasis Probe products, models CD-B610LA, CD-B612LA, CD-B620LA, and CD-B622LA. These products are designed to function as conventional electro-coagulation devices when supplied with current from a standard bipolar electrosurgical generator and are intended for coagulation of active bleeding lesions in the upper or lower gastrointestinal tracts during endoscopic procedures.

Customers should immediately discontinue using the BiCOAG Hemostasis Probe products, models, CD-B610LA, CD-B612LA, CD-B620LA, and CD-B622LA.

Reason for Action:
Olympus determined that the affected model numbers may have been manufactured without the designated amount of adhesive to the rear of the device's ceramic tip, which may result in detachment of the ceramic tip.

A comprehensive review of historical complaints during Olympus' investigation identified twenty-three (23) complaints determined to have a failure mode potentially applicable to the issue in scope of this notification. Of the twenty-three (23) complaints, five (5) were classified as serious injuries due to the device's ceramic tip having broken off during clinical use and falling into the patient.

The affected products have been discontinued and have not been produced since November 2024. Olympus is removing all remaining impacted products from the market.

Risk to Health:
Detachment of the ceramic tip may result in patient harm or disruption of the procedure. If identified during setup, the procedure may be delayed while a replacement device is obtained. If tip detachment occurs during use, the device may become unusable, requiring replacement and potentially prolonging the procedure. A detached tip may also separate into the patient, requiring endoscopic retrieval.

Additionally, tip detachment within the patient can result in sharp edges that may cause tissue injury or bleeding, potentially requiring endoscopic intervention. Exposed wires resulting from the detachment may also

unintentionally deliver RF energy to non-target tissue, potentially causing thermal injury or burns. However, continuous endoscopic visualization, user training, and standard procedural practices allow the clinician to promptly stop energy delivery and manage the issue, reducing the likelihood of patient harm and supporting safe completion of the procedure.

Actions Required:

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

1. Examine your inventory for the model number provided in this notice and immediately cease use and quarantine any affected products.
2. Olympus will arrange for the return of your device to Olympus. When it is received, you will receive a credit for your affected device.
3. Olympus requests that you acknowledge receipt of this letter. Indicate on the Response Form that you have received and understand this notification by filling out and returning the completed enclosed Response Form to us.
4. If you have further distributed this product, identify your customers and forwards this notification.

Olympus requests that you report any complaints including device detachment experienced with the use of this product to Olympus.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you have any questions or concerns, please do not hesitate to contact us for additional information.

Contact for enquiries

Regulatory Affairs and Quality Assurance Department
Email : mes-ra.oml@olympus.com
Tel : (603) 7650 8990
Fax : (603) 7650 8999

Yours sincerely,

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Hideki Nagai
Managing Director
Olympus (Malaysia) Sdn. Bhd

OLYMPUS

RESPONSE FORM
Medical Device Recall - Acknowledgement and Receipt

Response is required

[Name & Address of Hospital/Medical Facility]
[Dept/Attn]

Product: OLYMPUS Hemostasis Devices

Product Name	Model Number	Lot Numbers
BiCOAG Hemostasis Probe	**CD-B610LA** **CD-B612LA** **CD-B620LA** **CD-B622LA**	**All (within expiry date)**

Please distribute this information to the appropriate personnel at your facility, including surgeons who may have received the product which is the subject of this recall notice.

I have read and understand the recall instructions provided in the **10 August 2026** letter.

Yes ☐ No ☐

Any adverse incidents associated with recalled product?

Yes ☐ No ☐

If yes, please explain: _____

Check the applicable boxes below:

☐ I DO NOT have affected device remaining. All have been used or discarded.

☐ I DO have the affected device, which I will return to Olympus.

Lot Number (s):_____

Quantity to be Returned (UOM): _____

Additional Customer Feedback:

Name: _____

Designation: _____

…… ……

Signature & Company Stamp Date

Please send the completed and signed Response Form to Regulatory Affairs and Quality Assurance Department to
[Fax/Email : (603) 7650 8999 / mes-ra.oml@olympus.com]