Date: XX.XX.XXXX

Olympus reference: FY26-059-F Lower Amount of Adhesive Used for Bonding Ceramic Tips

URGENT: MEDICAL DEVICE RECALL/REMOVAL

RE: Olympus Hemostasis Devices

Attention: Operating Room / Endoscopy and Risk Management Departments

Material ID	Model Number	Material Description	Lot Numbers	UDI-DI
EGCD-B610LA	CD-B610LA	BiCOAG Hemostasis Probe	All (within expiry date)	00821925039469
EGCD-B612LA	CD-B612LA			00821925039476
EGCD-B620LA	CD-B620LA			00821925039483
EGCD-B622LA	CD-B622LA			00821925039452

Dear HealthCare Provider:

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 purchased 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 requests that you acknowledge receipt of this FSN. **Note:** This request applies even if you no longer have any affected product in your inventory.
3. If you have affected products in your inventory, please contact Olympus with regard to return of affected products. Olympus will issue a credit to your facility upon return of your affected product
4. If you have further distributed it, forward this notice to other users who may have affected products.

[If applicable:] Your National Competent Authority is aware of the actions described in this letter.

Olympus requests that you report any complaints, including device detachment to [local facility complaint reporting contact]. [If applicable:] Adverse events experienced with the use of this product may also be reported [local competent authority] by [method].

Olympus fully appreciates your prompt cooperation in addressing this situation. 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

REPLY FORM

FY26-059-F Lower Amount of Adhesive Used for Bonding Ceramic Tips

Facility name	
Facility Address	
Contact Name	
Contact E-mail Address	
Contact Telephone Number	

Insert description of the product names, lot numbers and quantity of the affected products remaining in your facility

Catalogue Number	Lot Number	Quantity

I acknowledge receipt of this notification. I confirm that I have further communicated to any affected departments.

Completed By:		
		Click or tap to enter a date.
Name	*Signature*	*Date (YYYY-MM-DD)*

Please send the completed form to XXX by date XXX.