Reference: 2026-X002M

12 January 2026

URGENT: MEDICAL DEVICE REMOVAL

Product: OLYMPUS Clevercut Sphincterotomes

Product Name	Model Number	Lot Numbers
CleverCut Single Use 3-Lumen Sphincterotome V	KD-V411M & KD-V431M	See Appendix 1

Attention: **Endoscopy Department, Risk Manager**

Dear Healthcare Professional,

Olympus is writing to inform you of a Medical Device Removal action pertaining to the CleverCut and FlowCut Sphincterotome. These instruments have been designed to be used with an Olympus endoscope and guidewire for papillotomy using high-frequency current.

Reason for Action:
Olympus has observed an increase in complaints regarding wire deformation in the CleverCut Sphincterotome devices. Preliminary investigations showed that units manufactured with a thermoforming process, which involves heating the assembly, so the device tip keeps the curved stylet's shape, are less likely to have an incorrect cutting wire orientation. Devices which did not undergo thermoforming could deform and lose performance. As a result, Olympus is removing lots where the devices may not have been manufactured with the thermoforming process.

Required Action: Cease use of the affected product immediately.

Risk to Health:

Deformation or incorrect orientation of a sphincterotome cutting wire, may be recognized during preparation of the device or while performing an ERCP procedure and can lead to potential patient harm(s). The most commonly reported patient harm associated with this issue are delays in initiation or performing procedures due to the requirement to replace or troubleshoot a device with an incorrectly oriented wire. The incorrect orientation of the cutting wire can cause unintended injury to patient anatomy, including bleeding and perforation of the hepatobiliary and/or the pancreatic system, requiring surgical or endoscopic intervention to treat. In some cases, improper wire positioning may cause the wire to break and/or detach, potentially leaving a wire fragment in the patient. This may require additional intervention for endoscopic retrieval, which could cause further complications such as bleeding or tissue injury.

Action Required:
Our records indicate that your facility has received one or more of the affected products.
Therefore, Olympus requests you to take the following actions:

1. Examine your inventory and quarantine any identified devices immediately.
2. **Immediately cease usage of any affected product in your inventory.**

3. Olympus will arrange for the return of your device to Olympus. When it is received, you will receive a credit for your affected device.
4. 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.
5. If you have further distributed this product, identify your customers and forwards this notification.

Olympus requests that you report any complaints and adverse events experienced with the use of this product to Olympus.

Olympus regrets any inconvenience caused and fully appreciates your prompt cooperation in addressing this matter. 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

The **Medical Device Authority** has been informed of this notice.

Yours sincerely,

Hideki Nagai
Hideki Nagai (Jan 13, 2026 16:59:09 GMT+8)

Hideki Nagai
Managing Director
Olympus (Malaysia) Sdn. Bhd

OLYMPUS

Appendix 1 – Affected Model, Lot

Model	Affected Lot
KD-V411M-0320	2YK, 2ZK, 31K, 32K, 33K, 34K, 35K, 36K, 37K, 38K, 39K, 3XK, 3YK, 3ZK, 41K, 42K, 43K, 44K, 45K, 46K, 47K, 48K, 49K, 4XK, 4YK, 4ZK, 51K, 52K, 53K, 54K, 55K, 56K, 57K, 58K, 59K, 5XK, 5YK, 2YV, 2ZV, 31V, 32V, 33V, 34V, 35V, 36V, 37V, 38V, 39V, 3XV, 3YV, 3ZV, 41V, 42V, 43V, 44V, 45V, 46V, 47V, 48V, 49V, 4XV, 4YV, 4ZV, 51V, 52V, 53V, 54V, 55V, 56V, 57V, 58V, 59V, 5XV, 5YV
KD-V431M-0730	2YK, 2ZK, 31K, 32K, 33K, 34K, 35K, 36K, 37K, 38K, 39K, 3XK, 3YK, 3ZK, 41K, 42K, 43K, 44K, 45K, 46K, 47K, 48K, 49K, 4XK, 4YK, 4ZK, 51K, 52K, 53K, 54K, 55K, 56K, 57K, 58K, 59K, 5XK, 5YK, 2YV, 2ZV, 31V, 32V, 33V, 34V, 35V, 36V, 37V, 38V, 39V, 3XV, 3YV, 3ZV, 41V, 42V, 43V, 44V, 45V, 46V, 47V, 48V, 49V, 4XV, 4YV, 4ZV, 51V, 52V, 53V, 54V, 55V, 56V, 57V, 58V, 59V, 5XV, 5YV

RESPONSE FORM

Medical Device Recall - Acknowledgement and Receipt

Response is required

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

Product: OLYMPUS Clevercut Sphincterotomes

Product Name	Model Number	Lot Numbers
CleverCut Single Use 3-Lumen Sphincterotome V	KD-V411M & KD-V431M	See Appendix 1

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 **12 January 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: _____ Quantity to be Returned (UOM): _____

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]

2026-X002M Recall - Customer Letter

Final Audit Report 2026-01-13

Created:	2026-01-12 (Korean Standard Time)
By:	Rohaya Binti Asib (rohaya.asib@olympus.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAA67IH1Tw2JNAb-uJMPsnBALh6w2DFf_Uc

"2026-X002M Recall - Customer Letter" History

Document created by Rohaya Binti Asib (rohaya.asib@olympus.com)
2026-01-12 - 12:10:46 PM GMT+9- IP address: 136.226.234.96

Document emailed to Hideki Nagai (hideki.nagai@olympus.com) for signature
2026-01-12 - 12:11:43 PM GMT+9

Email viewed by Hideki Nagai (hideki.nagai@olympus.com)
2026-01-13 - 5:00:22 PM GMT+9- IP address: 104.47.51.126

Document e-signed by Hideki Nagai (hideki.nagai@olympus.com)
Signature Date: 2026-01-13 - 5:59:09 PM GMT+9 - Time Source: server- IP address: 136.226.234.96

Agreement completed.
2026-01-13 - 5:59:09 PM GMT+9