

**URGENT: MEDICAL DEVICE REMOVAL****OLYMPUS CleverCut3V and FlowCut Sphincterotome**

| <b>Product Name</b>   | <b>Model Number</b>                          | <b>Lot Numbers</b> | <b>UDI DI</b>  |
|---|--|--------------------|--|
| CleverCut3V Single Use 3-Lumen Sphincterotome V             | KD-V411M & KD-V431M                          | See Appendix       | 14953170463775,<br>14953170183970,<br>14953170380553,<br>14953170380560,<br>14953170380577,<br>14953170380584,<br>14953170380591,<br>14953170380638,<br>14953170380645 |
| CleverCut3V Single Use Sphincterotome V (Distal Wireguided) | KD-VC411Q, KD-VC431Q, KD-VC433Q, & KD-VC412Q | See Appendix       | 14953170399296,<br>14953170399302,<br>14953170399319,<br>14953170399326,<br>14953170399333,<br>14953170399340,<br>14953170399357,<br>14953170399364,<br>14953170399371 |
| FlowCut Disposable Triple Lumen Sphincterotome              | KD-401Q, KD-411Q & KD-431Q                   | See Appendix       | 14953170463768,<br>14953170463775  |

Date: 07-JAN-2026

**Attention: Endoscopy Department, Risk Management**

Dear Healthcare Professional:

Olympus is writing to inform you of a Medical Device Removal action pertaining to the CleverCut3V and FlowCut Sphincterotome. This Medical Device Removal action only applies to the model and lot numbers listed in the Appendix. 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 CleverCut3V 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 devices 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.

**Actions Required:**

Our records indicate that your facility has received one or more affected devices. Olympus requires 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. Please contact Customer Service at 1-800-848-9024, option 2, to obtain a Return Material Authorization. Olympus will arrange for the return of your device to Olympus. Olympus will issue a credit to your facility upon receipt of your affected product.
4. Olympus requests that you acknowledge receipt of this letter through our recall web portal:
  - a. Go to <https://olympusamerica.com/recall>
  - b. Enter the recall number: "0487"
  - c. Complete the form as instructed.
5. If you have further distributed it, please forward this notice to other users who may have the affected products.

Olympus requests you to report any complaints to our Technical Assistance Center (TAC) at 1-800-848-9024, option 1, and the FDA. Adverse events experienced with the use of this 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 at [Cynthia.Ow@olympus.com](mailto:Cynthia.Ow@olympus.com) or by phone at (647) 999-3203.

Sincerely,

*Cynthia Ow*

Cynthia Ow  
Sr. Manager  
Field Corrective Action, Americas

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**OLYMPUS CleverCut3V and FlowCut Sphincterotome**

**Appendix – Affected Models and Lots**

| Model          | Affected Lot  |
|----------------|---|
| KD-V411M-0320  | 2YK, 2ZK,<br>31K, 32K, 33K, 34K, 35K, 36K, 37K, 38K, 39K, 3XK, 3YK, 3ZK,<br>41K, 42K, 43K, 44K, 45K, 46K, 47K, 48K, 49K, 4XK, 4YK, 4ZK,<br>51K, 52K, 53K, 54K, 55K, 56K, 57K, 58K, 59K, 5XK, 5YK,   |
| KD-V411M-0330  | 2YV, 2ZV,<br>31V, 32V, 33V, 34V, 35V, 36V, 37V, 38V, 39V, 3XV, 3YV, 3ZV,<br>41V, 42V, 43V, 44V, 45V, 46V, 47V, 48V, 49V, 4XV, 4YV, 4ZV,<br>51V, 52V, 53V, 54V, 55V, 56V, 57V, 58V, 59V, 5XV, 5YV  |
| KD-V411M-0720  | 2ZV,<br>31V, 32V, 33V, 34V, 35V, 36V, 37V, 38V, 39V, 3XV, 3YV, 3ZV,<br>41V, 42V, 43V, 44V, 45V, 46V, 47V, 48V, 49V, 4XV, 4YV, 4ZV,<br>51V, 52V, 53V, 54V, 55V, 56V, 57V, 58V, 59V, 5XV, 5YV,<br>2ZV,<br>31V, 32V, 33V, 34V, 35V, 36V, 37V, 38V, 39V, 3XV, 3YV, 3ZV,<br>41V, 42V   |
| KD-V411M-0725  |   |
| KD-V411M-0730  |   |
| KD-V411M-1520  |   |
| KD-V411M-1530  |   |
| KD-V411M-3020  |   |
| KD-V411M-3025  |   |
| KD-V411M-3030  |   |
| KD-V431M-0720  | 2YK, 2ZK,<br>31K, 32K, 33K, 34K, 35K, 36K, 37K, 38K, 39K, 3XK, 3YK, 3ZK,<br>41K, 42K, 43K, 44K, 45K, 46K, 47K, 48K, 49K, 4XK, 4YK, 4ZK,<br>51K, 52K, 53K, 54K, 55K, 56K, 57K, 58K, 59K, 5XK, 5YK,<br>2YV, 2ZV,<br>31V, 32V, 33V, 34V, 35V, 36V, 37V, 38V, 39V, 3XV, 3YV, 3ZV,<br>41V, 42V, 43V, 44V, 45V, 46V, 47V, 48V, 49V, 4XV, 4YV, 4ZV,<br>51V, 52V, 53V, 54V, 55V, 56V, 57V, 58V, 59V, 5XV, 5YV |
| KD-V431M-0730  |   |
| KD-VC411Q-0320 |   |
| KD-VC411Q-0330 |   |
| KD-VC411Q-0720 |   |
| KD-VC411Q-0725 |   |
| KD-VC411Q-0730 |   |
| KD-VC412Q-0215 |   |
| KD-VC431Q-0720 |   |
| KD-VC431Q-0730 |   |
| KD-VC433Q-0720 |   |
| KD-VC433Q-0730 |   |
| KD-401Q-0320   |   |
| KD-401Q-0330   |   |
| KD-401Q-0720   |   |
| KD-401Q-0725   |   |
| KD-401Q-0730   | 2YK, 2ZK,<br>31K, 32K, 33K, 34K, 35K, 36K, 37K, 38K, 39K, 3XK, 3YK, 3ZK,<br>41K, 42K, 43K, 44K, 45K, 46K, 47K, 48K, 49K, 4XK, 4YK, 4ZK,<br>51K, 52K, 53K, 54K, 55K, 56K, 57K, 58K, 59K, 5XK, 5YK,   |
| KD-411Q-0720   | 2YV, 2ZV,<br>31V, 32V, 33V, 34V, 35V, 36V, 37V, 38V, 39V, 3XV, 3YV, 3ZV,<br>41V, 42V, 43V, 44V, 45V, 46V, 47V, 48V, 49V, 4XV, 4YV, 4ZV  |
| KD-411Q-0730   | 51V, 52V, 53V, 54V, 55V, 56V, 57V, 58V, 59V, 5XV, 5YV   |
| KD-431Q-0720   | 51V, 52V, 53V, 54V, 55V, 56V, 57V, 58V, 59V, 5XV, 5YV   |