Date: *XX.XX.XXXX*

Olympus Reference: QIL FY26-EMEA-21-FY26-058 Single Use Sphincterotome Wire Deformations

URGENT FIELD SAFETY NOTICE

RE: OLYMPUS CleverCut and FlowCut Sphincterotomes
Attention: Endoscopy Department, Risk Management

Affected Products:

Material	Model	Product Name	Lot Number(s)	UDI-DI
N1089530 N5411130 N5411230 N5411330 N5411430 N5411530 N5411630 N5411730 N5411830 N5411930 N5412030	KD-V411M & KD-V431M	CleverCut Single Use 3-Lumen Sphincterotome V	See Attachment 1	14953170183994 14953170380553 14953170380560 14953170380577 14953170380584 14953170380591 14953170380607 14953170380614 14953170380621 14953170380638 14953170380645
N5777330 N5777430 N5777530 N5777630 N5777730 N5777830 N5777930	KD-VC411Q, KD-VC431Q, KD-VC433Q, & KD-VC412Q	CleverCut Single Use Sphincterotome V (Distal Wireguided)	See Attachment 1	14953170399296 14953170399302 14953170399319 14953170399326 14953170399333 14953170399340 14953170399357
025895 025896 025897 025898 025899	KD-401Q, KD-411Q & KD-431Q	FlowCut Disposable Triple Lumen Sphincterotome	See Attachment 1	14953170041584 14953170041614 14953170041645 14953170041676 14953170041706

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 and FlowCut 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.

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. 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. Olympus requests that you acknowledge receipt of this letter *[local facility method/contact].*
5. Please forward this notice to other users who may have the affected products if you have further distributed it.

[If applicable:] [competent authority] is aware of the actions described in this letter.
Olympus requests that you report any complaints 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

ATTACHMENT 1 – Affected Model, Lot

Material	Model	Lot Number(s)
025895	KD-401Q-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
025896	KD-401Q-0330	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

025897	KD-401Q-0720	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
025898	KD-401Q-0725	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
025899	KD-401Q-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
N1089530	KD-V411M-0330	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
N5411130	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
N5411230	KD-V411M-0330	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
N5411330	KD-V411M-0720	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
N5411430	KD-V411M-0725	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
N5411530	KD-V411M-0730	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
N5411630	KD-V411M-1520	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
N5411730	KD-V411M-1530	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

N5411830	KD-V411M-3030	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
N5411930	KD-V431M-0720	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
N5412030	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
N5777330	KD-VC411Q-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
N5777430	KD-VC411Q-0330	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
N5777530	KD-VC411Q-0720	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
N5777630	KD-VC411Q-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
N5777730	KD-VC412Q-0215	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
N5777830	KD-VC431Q-0720	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
N5777930	KD-VC431Q-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

REPLY FORM – QIL FY26-EMEA-21-FY26-058 Single Use Sphincterotome Wire Deformations

Facility Name	
Facility Address	
Contact Name	
Additional Customer Requests (Indicate if you have any additional requests to support this action)	

Insert Catalogue Number, Lot Number 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*.