Date: 09/01/2026

Olympus Reference: QIL FY26-EMEA-14-FY26-903-F KD-645L & KD-640L

URGENT FIELD SAFETY NOTICE

RE: Triangle Tip Knife J – Single Use Electrosurgical Knives
Attention: Endoscopy Department, Operating Room, Risk Management

Affected Products:

Material	Model	Product Name	Lot Number(s)	UDI-DI
N2119630	KD-640L	Single Use Electrosurgical	See Attachment	04953170208423
N5412530	KD-645L	Single Use Electrosurgical	See Attachment	04953170407857

*See Attachment 1 for the full list of lot numbers

Dear Healthcare Provider:

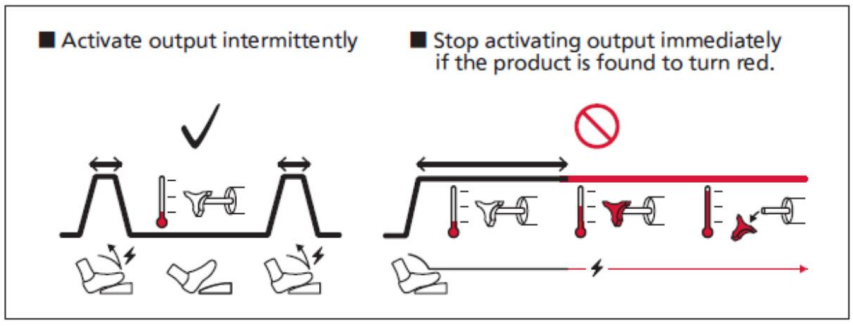
Olympus is writing to inform you of a Field Corrective Action pertaining to the KD-640L and KD-645L Triangle Tip Electrosurgical Knives. The Triangle Tip Electrosurgical Knives are single-use and are designed to be used with Olympus endoscopes and electrosurgical units. The KD-640L knife is intended to cut tissue using high-frequency current within the upper digestive tract. The KD-645L knife is intended to cut tissue using high-frequency current and flushing devices for submucosal injection within the digestive tract.

Reason for Action:
Olympus' investigation, after receiving complaints about the triangle tip of the KD-640L and KD-645L Triangle Tip Electrosurgical Knives breaking off during use, determined that deterioration of the cutting knife, caused by overheating and burning, can contribute to tip breakage during use.

Per the Warnings in the IFU (listed below), users should only activate the device output intermittently and should stop activating the output immediately if the device's triangle tip turns red.

Olympus is also notifying users of the following updates to the Instructions for Use and labeling:

- Addition of the following **visual aid** to more clearly communicate these instructions to users.



- Revision to the following statement in the KD-640L Instructions for Use from a Caution to a Warning:
  WARNING: Do not activate the high-frequency current while the triangle tip is not contacting the tissue, when the tissue is carbonized or when carbonized tissue adheres to the triangle tip or cutting knife. Otherwise, excessive current discharge may result in unintended injuries to the non-target tissue. If the triangle tip turns red due to continued excessive discharge, immediately shut off the power supply to prevent thermal damage to the tissue. If the cutting knife is withdrawn in the outer sheath at this time, the triangle tip may be dropped.

As a reminder, the following existing Warnings listed in the respective Instructions for Use regarding appropriate activation of the KD-640L and KD-645L electrosurgical knives should be followed:

KD-640L

- WARNING: When the electrosurgical unit is used in the coagulation mode, deformation or break of the cutting knife and the triangle tip could occur, for example when the high-frequency output is set too high or the length of the contact between the cutting knife and tissue is too short. During treatment, always ensure that the slider slides on the handle smoothly and that the electrosurgical knife observed in the endoscopic image is normal. Should deformation or break of the cutting knife be detected during use, immediately shut off the power supply, discontinue the procedure, pull the slider and withdraw the endoscope from the patient with the cutting knife retreated in the coated outer sheath. Do not continue using an abnormal electrosurgical knife to prevent perforation or bleeding. If the triangle tip and/or cutting knife is detached, be sure to collect it using grasping forceps.

KD-645L

- WARNING: Stop activating output immediately if the triangle tip and the cutting knife are found to turn red while activating output. Keeping output activated while the triangle tip and the cutting knife are red may result in thermal injury. Detachment of the triangle tip and deformation/break of the triangle tip, and cutting knife may also occur.
- WARNING: Do not activate output continuously but activate it intermittently. Continuous activation may result in patient injury, such as bleeding, tissue damage, or thermal injury of non-target tissue. Breakage or deformation of the triangle tip, and cutting knife may likely occur.

Risk to Health:

Use of these devices in a manner inconsistent with the IFU may lead to patient harms such as device tip/fragments breaking off into the patient. This may result in prolongation of surgery and therefore, anesthesia, and the potential for unexpected imaging or additional procedures/surgery for foreign body retrieval. Additional harms may include burns, perforation, foreign body reaction if device tip is unable to be located inside the patient, and possible aspiration for procedures done in the area of the hypopharynx.

Actions Required:

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

1. Carefully read the content of this notification.
2. Ensure all personnel are completely knowledgeable and thoroughly trained on the content of this notification, including the instruction for intermittent output activation and applicable Warnings and Cautions.
3. Keep a copy of this notification with the Instructions for Use for any affected devices remaining in your inventory.
4. If you have further distributed this product, identify them and forward this notification.
5. Olympus requests that you acknowledge receipt of this letter. Indicate on the Reply Form that you have received and understood this notification by filling out and returning the completed enclosed Reply Form back to your local Olympus representative at ra@olympus.co.uk latest by 02/02/2026.

The Medicines and Healthcare products Regulatory Agency (MHRA) is aware of the actions described in this letter. Olympus requests that you report any complaints, including breakage of the electrosurgical knife triangle tip, to concerns@olympus.co.uk. Adverse events experienced with the use of this product may also be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) online.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact me directly at charlotte.bell@olympus.com or Olympus directly at 01702 616333 from Monday through Friday or by e-mail at ra@olympus.co.uk

Sincerely,

Charlotte Bell
Field Safety Corrective Actions & Quality Assurance Projects Manager

ATTACHMENT 1 – Affected Model, Lot

KD-640L

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	58K	59K

KD-645L

2ZK	31K	32K	33K	34K	35K	36K	37K
38K	3XK	3YK	3ZK	42K	43K	44K	45K
46K	47K	48K	49K	4XK	4YK	4ZK	51K
52K	53K	54K	55K	56K	57K	58K	59K
5XK							

REPLY FORM – QIL FY26-EMEA-14-FY26-903-F KD-645L & KD-640L

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

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 ra@olympus.co.uk by 02/02/2026.