

Reference: 2025-008M

17 December 2025

URGENT - FIELD SAFETY NOTICE

To all users of **Olympus Triangle Tip Knife J – Single Use Electrosurgical Knives**

Product Name	Model Number	Lot Number(s)
Single Use Electrosurgical Knife	KD-645L	See Attachment 1

* See Attachment 1 for the full list of lot numbers

Re: Olympus to Reinforce the Warnings in the IFU.

Attention: Endoscopy Department, Operation Room, Risk Management

Dear Healthcare Professional:

Olympus is writing to inform you of a Field Corrective Action pertaining to the 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-645L knife is intended to cut tissue using high-frequency current and flushing devices for submucosal injection within the digestive tract.

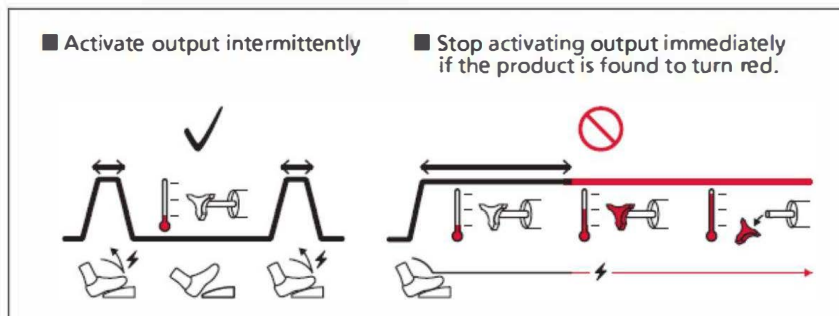
Reason for Action:

Olympus' investigation, after receiving complaints about the triangle tip of the KD-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.



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

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.

Olympus requests 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 and return the 'Response Form' to us.

Olympus requests that you report any complaints, including breakage of the electro-surgical knife triangle tip, and adverse events experienced with the use of this product to Olympus.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact us.

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

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Hideki Nagai
Managing Director
Olympus (Malaysia) Sdn. Bhd



ATTACHMENT 1 – Affected Model, Lot

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							

Response Form

Please send the complete and signed Response Form to Regulatory Affairs and Quality Assurance Department at:

To : Olympus (Malaysia) Sdn. Bhd, Regulatory Affairs & Quality Assurance
Fax/Email : (603) 7650 8999 / mes-ra.oml@olympus.com
From : _____ [Facility Name] Contact no.: _____
Date : _____
Ref : 2025-008M

URGENT - FIELD SAFETY NOTICE

Re: Olympus to Reinforce the Warnings in the IFU.

I acknowledge receipt of the Field Safety Notice ("FSN") referenced above. I confirm that I have further communicated to any affected departments.

Check the applicable boxes below:

- I DO NOT have affected product remaining. Product has been condemned or discarded.
- I DO have the affected product, which I will adhere to this FSN letter.

Additional Customer Requests:

(Indicate if you have any additional requests to support this action)

Name: _____

Designation: _____

.....
Signature & Company Stamp

.....
Date






2025-008M FSN Customer Letter

Final Audit Report

2025-12-16

Created:	2025-12-16 (Korean Standard Time)
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"2025-008M FSN Customer Letter" History

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