Reference: 2026-X004M

2 March 2026

URGENT: MEDICAL DEVICE REMOVAL

Product: OLYMPUS PK Cutting Forceps

Product Name	Model/Catalog Number	Serial/Lot Number(s)
3005PK PKS Cutting Forceps, 5mm x 33cm, 5/bx	3005PK	All Unexpired

Attention: **Urology Department, Gynecology Department, Surgical Department, Operating Room, Risk Management.**

Dear Healthcare Professional,

Olympus is writing to inform you of a Field Corrective Action. This Field Corrective Action pertains to the products listed in the table above. The cutting forceps are intended for electrosurgical coagulation, mechanical cutting, dissection, and grasping of tissue during laparoscopic and general surgical procedures, including open surgery where applicable, when used in accordance with the applicable instructions for use and compatible electrosurgical generators.

Immediately cease usage of any affected products in your inventory.

Reason for Action:

It was identified that the Everest Bipolar 5 mm Cutting Forceps, PK® Cutting Forceps 5 mm, HALO™ PKS™ Cutting Forceps, and PKS™ Cutting Forceps contain supplied components for which the supplier did not adequately validate the welding process. Defective welds can result in the cutting forceps' jaws breaking during clinical use. As a result of this issue, Olympus is requesting customers to return affected products.

Risk to Health:

The tip/jaw assembly breaking off the end of the cutting forceps can lead to potential patient harms. A broken jaw assembly may lead to a delay in initiating a procedure or a foreign body (jaw assembly) in the patient, potentially requiring imaging and prolonged operative time to locate and remove the broken piece. Additionally, tissue damage could occur due to exposed sharp edges.

Olympus has received 19 complaints related to these products, 18 of which were reported as serious injuries.

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. Carefully read the content of this notification.
2. Examine your inventory and quarantine any affected devices.
3. Cease usage of the product with immediate effect.

4. Olympus will arrange for the return of your device to Olympus. When it is received, you will receive a credit for your affected device.
5. 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.
6. 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 (Mar 2, 2026 15:02:18 GMT+8)

Hideki Nagai
Managing Director
Olympus (Malaysia) Sdn. Bhd

RESPONSE FORM

Medical Device Recall - Acknowledgement and Receipt

Response is required

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

Product: OLYMPUS PK Cutting Forceps

Product Name	Model/Catalog Number	Serial/Lot Number(s)
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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 **2 March 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-X004M Recall Customer Letter (1)

Final Audit Report 2026-03-02

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