Reference: 2024-X001M

9 January 2024

URGENT: MEDICAL DEVICE REMOVAL
Product: ESG PK CUTTING FORCEPS, 5MM, 33CM
Model: PK-CF0533
Lot Number: FR240430

Attention: **Surgical Department, Risk Management**

Dear Healthcare Professional:

Olympus (Gyrus ACMI, Inc.) is writing to inform you of a removal action for the PK-CF0533 ESG PK Cutting Forceps device in response to an increased occurrence of jaw breakage. The PK Cutting Forceps is indicated for electrosurgical coagulation, mechanical cutting, and grasping of tissue during the performance of laparoscopic and open general surgical procedures. It is intended to be used with the Olympus Electrosurgical Generator ESG-400 and ESG-410 only.

Olympus is taking this removal action after identifying an increasing trend in complaints received for jaw breakage of the PK Cutting Forceps. Olympus has received eighteen (18) complaints for this issue and sixteen (16) of these complaints were reported as serious injuries. The jaw may fracture prior to the procedure during the inspection instructed per the IFU, or during the procedure. Through our investigation, Olympus has determined that the issue impacts lots manufactured between March 2022 to December 2023.

Risk to Health

The jaw breaking off the device during use may require unexpected device replacement during the procedure potentially causing surgical delays or prolonged surgical procedures. Additional patient harms associated with this device issue include foreign body in patient with requirement for removal, tissue injury, bleeding, and additional imaging or conversion to open procedure if clinician is unable locate the broken jaw component.

Action steps to be taken by end user:

Our records indicate that your facility has received one or more affected units. **Olympus requests you to take the following actions:**

1. **Inspect your inventory and identify** any products of the model and lots subject to this action. Please check all areas of the hospital to determine if any of these devices remain in inventory. **Quarantine and cease use** of the affected lot.

2. If you have distributed these devices outside your facility, please provide a copy of this letter to those facilities immediately.

OLYMPUS (MALAYSIA) SDN. BHD. (200101010901)
Unit T2-L05-1, PJ33, No. 3, Jalan Professor Khoo Kay Kim, Section 13, 46200 Petaling Jaya, Selangor, Malaysia
Tel: (603) 7650 8990 Fax: (603) 7650 8999

3. Olympus requests that you acknowledge receipt of this letter and return the 'Response Form' to us.

4. Olympus will contact you to return any identified affected product from your facility. Olympus will issue a credit to your facility for your affected product.

Olympus requests that you report complaints, including jaw breakage 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

Yours sincerely,

Hideki Nagai
……
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 NAME: ESG PK CUTTING FORCEPS, 5MM, 33CM
Model: PK-CF0533
Lot Number: FR240430

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 **9 Jan 2024** 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 devices remaining. All have been used or discarded.

☐ I DO have the affected devices, 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 Department to
[Fax/Email : (603) 7650 8999 / mes-ra.oml@olympus.com]

OLYMPUS (MALAYSIA) SDN. BHD. (200101010901)
Unit T2-L05-1, PJ33, No. 3, Jalan Professor Khoo Kay Kim, Section 13, 46200 Petaling Jaya, Selangor, Malaysia
Tel: (603) 7650 8990 Fax: (603) 7650 8999

2024-X001M Recall - Customer Letter

Final Audit Report 2024-01-09

Created:	2024-01-09
By:	Seo Ching Yeoh (seoching.yeoh@olympus.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAUGhU6l_Zl3HmUgavDwfE20Jx4X7PeNRk

"2024-X001M Recall - Customer Letter" History

Document created by Seo Ching Yeoh (seoching.yeoh@olympus.com)
2024-01-09 - 5:53:28 AM GMT

Document emailed to Hideki Nagai (hideki.nagai@olympus.com) for signature
2024-01-09 - 5:54:05 AM GMT

Email viewed by Hideki Nagai (hideki.nagai@olympus.com)
2024-01-09 - 7:56:35 AM GMT

Document e-signed by Hideki Nagai (hideki.nagai@olympus.com)
Signature Date: 2024-01-09 - 7:57:00 AM GMT - Time Source: server

Agreement completed.
2024-01-09 - 7:57:00 AM GMT