

January 15, 2024

URGENT: MEDICAL DEVICE REMOVAL

Name: ESG PK CUTTING FORCEPS, 5MM, 33CM

Model: PK-CF0533

Lot Numbers: Attached

UDI-DI: 00821925035867

Attention: Operating Room, 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 device 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 device jaw breakage of the PK Cutting Forceps. Olympus has received eighteen (18) complaints for this issue, with sixteen (16) of these reported complaints classified as Serious Injuries due to foreign body in patient, and two (2) of these complaints classified as Malfunctions. 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

If the device jaw breaks off during use, the users cannot grasp and/or coagulate tissue, and 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.

Actions to be taken by the 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 model/lots. The lot number can be found on the outer box or the immediate pouch (see picture below).



Location of lot number on box (left) and pouch (right)

- Please contact Customer Service** at 1-800-848-9024, option 2, with the quantity, model and lot number of the affected device(s). Olympus will issue a Return Material Authorization to return any affected product at no charge. Olympus will issue a credit to your facility upon return of the affected product.
- Access the Olympus recall portal to indicate that you have received this notification.**
 - Go to <https://olympusamerica.com/recall>.
 - Enter the recall number "0438"
 - Complete the form as instructed.
- If you have distributed these devices outside your facility, please provide a copy of this letter to those facilities immediately.

Olympus requests you to report any complaints, including jaw breakage, to the Technical Assistance Center (TAC) at 1- 800-848-9024, option 1, and the FDA. Adverse events experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact me directly by phone at (647) 999-3203 or by e-mail at Cynthia.Ow@olympus.com.

Sincerely,

Cynthia Ow

Cynthia Ow
FCA Regional Lead, Americas



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List of Affected Model and Lot Numbers

Model	UDI	Name
PK-CF0533	00821925035867	ESG PK CUTTING FORCEPS, 5MM, 33CM

Affected Lot Numbers				
FR258486	FR212413	FR240430	FR303799	FR316869
FR261738	FR212735	FR246627	FR297022	FR319703
FR259544	FR215061	FR247039	FR301062	FR316872
FR263183	FR216817	FR248008	PW308561	FR327890
FR276278	FR220525	FR255679	PW308562	PW308972
FR279757	FR222456	FR248312	PW308563	FR335984
FR279625	FR227254	FR263636	PW308560	FR335990
FR279658	FR227774	FR263244	PW308567	FR337947
FR286369	FR227781	FR269280	PW308566	FR373912
FR287112	FR232882	FR269267	PW308565	FR401646
FR374622	FR234845	FR269269	FR303864	FR379790
FR207935	FR247614	FR287114	FR313639	FR347006