



Date: January XX, 2024

Olympus Reference: QIL FY24-EMEA-34-FY24-OSTA-14-PK-CF0533 Jaw Breakage

**URGENT FIELD SAFETY NOTICE**

**Product:** PK CUTTING FORCEPS,5MM.33CM.5stk.

**Recall of certain lot numbers** (please refer to Attachment 1)

**Attention:** Surgery Department, Risk Management Department

Material ID	Model	Name	Lot
EGPK-CF0533	PK-CF0533	PK CUTTING FORCEPS,5MM.33CM.5stk.	Please see attached list

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 , 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 of 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 the end user:**

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

1. Carefully read the content of this Field Safety Notice (FSN).

2. **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.
3. Contact your Olympus customer service representative by [Regional contact]. Olympus will issue a credit to your facility upon return of affected product.
4. If you have distributed these devices outside your facility, please notify your customers of this matter immediately by forwarding them this Field Safety Notice. Please appropriately document your notification process and let us know the end-customer feedback accordingly.
5. Indicate on the Reply Form that you have received and understood this Field Safety Notice by filling out and returning the completed enclosed Reply Form back to your local Olympus representative latest by **XX.XX.XXXX**.

**Your National Competent Authority** is aware of the actions described in this letter.

Olympus requests that you report complaints to **[Regional Complaint Intake Contact]**. **[Region to include as applicable]** Adverse events experienced with the use of this product may also be reported to **[Regional to revise to local competent authority]** by **[competent authority contacts]**.

Sincerely,

[SIGNATORY]

[Contact Name]

## List of Affected Model and Lot Numbers

Model	Name
PK-CF0533	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



**REPLY FORM – QIL FY24-EMEA-34-FY24-OSTA-14-PK-CF0533 Jaw Breakage**

<b>OLYMPUS URGENT FIELD SAFETY NOTICE</b> <b>Market removal of certain lot numbers of</b> <b>PK CUTTING FORCEPS,5MM.33CM.5stk</b>		
<b>[Name &amp; Address of Hospital/Medical Facility]</b>		
<b>[Dept/Attn]</b>		
<b>[Date]</b>		
<b>[Inventory information]</b>		
<b>Model Name</b>	<b>Lot Numbers</b>	<b>Quantity</b>

I herewith acknowledge the receipt of your Field Safety Notice.  
Further I confirm that I have transferred the content of the attached FSN to all affected departments on which this action has an impact.

Name (Signature) \_\_\_\_\_

Name (Print) \_\_\_\_\_

Position \_\_\_\_\_

Please send your completed paper form response to XXXXX <mailto:>latest by XXXX.