Date: 03-March-2026

Olympus reference: QIL FY26-EMEA-26-FY26-062-F Sub-tier supplier

URGENT: FIELD SAFETY NOTICE

RE: OLYMPUS PK/PKS/Everest Cutting Forceps

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

Material ID	Model/Catalog Number	Product Name	Lot Number(s)	UDI DI
EGPK-CF0533 K10027741	PK-CF0533	PK-CF0533 PK Cutting Forceps, 5mm x 33cm	All unexpired	00821925035867
EGHACF0533 K10022068	HACF0533	HACF0533 HALO PKS Cutting Forceps, 5mm x 33cm, 5/bx	All unexpired	00821925036390
EG920005PK	920005PK	920005PK PKS Cutting Forceps w/Cord, 5mm x 33cm, 5/bx	All unexpired	00821925036178
EG3005	3005	3005 Everest Cutting Forceps, 5mm x 33cm, 5/bx	All unexpired	00821925035881
EG3006-020 K10015952	3006	3006 Everest Cutting Forceps w/Cord, 5mm x 33cm, 5/bx	All unexpired	00821925035898
EG3005PK	3005PK	3005PK PKS Cutting Forceps, 5mm x 33cm, 5/bx	All unexpired	00821925036000
EG920000PK K10010033	920000PK	920000PK PKS Cutting Forceps w/Cord, 5mm x 24cm, 5/bx	All unexpired	00821925038080
EG3025-020	3025	3025 Everest Cutting Forceps, 5mm x 24cm, Design III, 5/bx	All unexpired	00821925041547
EG3025PK3	3025PK	3025PK PKS Cutting Forceps, 5mm x 24cm, 5/bx	All unexpired	00821925036024

Dear Healthcare Professional /Provider:

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.

Actions Required:
Our records indicate that your facility has purchased one or more of the affected products. Therefore, Olympus requires you to take the following actions:

1. Carefully read the content of this notification.
2. Examine your inventory and quarantine any affected devices immediately.
3. **Immediately cease usage of the product.**
4. Ensure all users of the device carefully read the content of this notification.
5. If you have affected products in your inventory, please contact Olympus with regard to return of affected products. Olympus will issue a credit to your facility upon return of your affected product.
4. Olympus requests that you acknowledge receipt of this letter. Indicate on the Reply Form that you have received and understand this notification by filling out and returning the completed enclosed Reply Form to your local Olympus representative XXX.
5. If you have further distributed this product, identify your customers, and forward this notification to them.

Your National Competent Authority is aware of the actions described in this notification

Olympus requests that you report any complaints, including breakages and detaching components, to *[local facility complaint reporting contact]*. Adverse events experienced with the use of this product may also be reported to *[local competent authority]* by *[method].*

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact *[me directly at XXXX@olympus.com/ Olympus directly at (XXX) XXX-XXXX from Monday through Friday or by e-mail at XXX].*

Sincerely,
Name
Olympus title

REPLY FORM - QIL FY26-EMEA-26-FY26-062-F Sub-tier supplier

Facility Name	
Facility Address	
Contact Name	
Contact E-mail Address	
Contact Telephone Number	

Insert catalogue number(s), lot number(s) and quantity of the affected products, which remain in your inventory.

Catalogue Number	**Lot Number**	**Quantity**

I acknowledge receipt of this notification. I confirm that I have communicated further to any affected departments.

Completed By:		
		Click or tap to enter a date.
Name	*Signature*	*Date (YYYY-MM-DD)*

Please send the completed form to *XXX*