OLYMPUS

URGENT: MEDICAL DEVICE REMOVAL

PK, PKS, HALO PKS and Everest Cutting Forceps

Product Name	Model/Catalog Number	Lot Number(s)	UDI PI
PK-CF0533 PK Cutting Forceps, 5mm x 33cm	PK-CF0533	All Unexpired	00821925035867
HACF0533 HALO PKS Cutting Forceps, 5mm x 33cm, 5/bx	HACF0533	All Unexpired	00821925036390
920005PK PKS Cutting Forceps w/Cord, 5mm x 33cm, 5/bx	920005PK	All Unexpired	00821925036178
3005 Everest Cutting Forceps, 5mm x 33cm, 5/bx	3005	All Unexpired	00821925035881
3006 Everest Cutting Forceps w/Cord, 5mm x 33cm, 5/bx	3006	All Unexpired	00821925035898
3005PK PKS Cutting Forceps, 5mm x 33cm, 5/bx	3005PK	All Unexpired	00821925036000
920000PK PKS Cutting Forceps w/Cord, 5mm x 24cm, 5/bx	920000PK	All Unexpired	00821925038080

Date: 25-FEB-2026

Attention: Surgical Department, Operating Room, Risk Management

Dear Healthcare Professional /Provider:

Olympus is writing to inform you of a Medical Device Removal action. This 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 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.

Olympus has received 19 complaints related to these products, 18 of which were classified as serious injury by Olympus.

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.

Actions Required:

Our records indicate that your facility has received one or more affected units. 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. Please contact Customer Service at 1-800-848-9024, option 2, to obtain a Return Material Authorization. Olympus will issue a credit to your facility upon receipt of your affected product.
5. Even if you no longer have the device, Olympus requests that you acknowledge receipt of this letter through the Olympus web portal:
    a. Go to https://olympusamerica.com/recall
    b. Enter the recall number "0493"
    c. Complete the form as instructed.
6. Please forward this notice to other users who may have the affected products if you have further distributed it.

Olympus requests you to report any complaints, including device breakage, to our 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 by phone at (647) 999-3203 or by email at Cynthia.Ow@Olympus.com.

Sincerely,

Cynthia Ow

Cynthia Ow
Sr. Manager
Field Corrective Action, Americas