Date: July 1, 2024

URGENT: MEDICAL DEVICE REMOVAL

OLYMPUS Everest Bipolar Cutting Forceps

Product Name	Model/Catalog Number	UDI-DI	Batch Numbers
Olympus Everest Bipolar Cutting Forceps	*3000*	N/A	*Reference attachment*
	3005	00821925035881	
	3006	00821925035898	

Attention: Surgical Department or Risk Management

Dear Healthcare Professional /Provider:

Olympus is writing to inform you of a Field Corrective Action pertaining to the Everest Bipolar Cutting Forceps, *models 3000, 3005 & 3006*. The cutting forceps are intended to be used with the bipolar outputs of compatible electrosurgical generators for use in laparoscopic and general surgical procedures.

Reason for Action:

Olympus has received 15 complaints during the December 2018 – December 2023 timeframe from customers indicating fractures and breakages in packaging trays and Tyvek covers which may lead to a sterility breach. The root cause of the broken trays is related to a packaging change. Olympus has received no reports of adverse events related to the identified issue.

Risk to Health:

Good Clinical Practice includes examination of all materials prior to being used for a procedure, during setup. This includes inspection of the device packaging for damage or signs of sterility breach, indicating that the contents inside the packaging may be compromised. Use of products with damaged trays where sterility may be compromised can lead to patient infection. Identification of damaged trays, if observed prior to a procedure, may result in delay to treatment while a replacement is obtained, and care should be taken while handling trays with fractures/cracks to avoid user injury (e.g. abrasions).

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 identify the above listed device(s) with the affected batch number.
3. Please contact Customer Service at 1-800-848-9024, option 2, to obtain a Return Material Authorization. Olympus will arrange for the return of your device to Olympus. When it is received, you will receive a credit for your affected device(s).
4. Olympus requests that you acknowledge receipt of this letter. Access the Olympus recall portal to indicate that you have received this notification.
    a. Go to https://olympusamerica.com/recall
    b. Enter the recall number "0449"
    c. Complete the form as instructed and include your account ID number.
5. If you have further distributed this product, identify your customers, and forward them this notification.

Olympus requests that you report any complaints, including package damage or signs of sterility breach, 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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Attachment – Batch Numbers

Model	Batch Number	Model	Batch Number
3000	FR150448	**3006**	FR145210
	FR154445		FR150478
	FR173022		FR163740
3005	FR137723		FR165213
	FR139935		FR177466
	FR141534		FR179534
	FR145203		FR179557
	FR157420		FR188129
	FR165250		FR200177
	FR176934		FR215047
	FR179541		FR220528
	FR197926		FR220979
	FR204443		FR224466
	FR206007		FR234887
	FR207123		FR248322
	FR214689		FR253501
	FR215012		FR255664
	FR215026		FR263141
	FR246906		FR269277
	FR261731		FR276180
	FR297010		FR287091
	FR305512		FR303624
	FR308131		FR305537
	FR335638		FR316877
	FR335650		FR378738
	FR378737		FR388883
	FR390629		PW308633
	FR397748		PW308686
	PW308683		PW308722
			PW308723