Date: XX.XX.XXXX

Olympus reference: QIL FY25-EMEA-10-FY25-001 Broken Forceps Trays

URGENT FIELD SAFETY NOTICE

RE: Olympus Everest Bipolar Cutting Forceps

Attention: *Surgical Endoscopy, Risk Manager or Materials Manager*

Product Name	Material ID	Batch Numbers	UDI-DI
Olympus Everest Bipolar Cutting Forceps	**EG3005**	**FR137723, FR139935, FR141534, FR145203, FR157420, FR165250, FR176934, FR179541, FR197926, FR204443, FR206007, FR207457, FR214689, FR215012, FR215026, FR224366, FR236105, FR246906, FR253500, FR253627, FR263139, FR279705, FR297010, FR305512, FR306890, FR308131, FR335638, FR335650, FR378888, FR390629, FR397748, FR401650, FR413631, PW308683, PW308684**	**00821925010093**
	EG3006-020	**FR145210, FR150478, FR163740, FR165213, FR177466, FR179534, FR179557, FR200177, FR215047, FR220528, FR220979, FR234887, FR248322, FR255664, FR263141, FR269277, FR276180, FR287091, FR305537, FR316877, FR328723, FR388883, PW308633, PW308686, PW308722, PW30872EG**	**00821925010703**

Dear Healthcare Professional /Provider:

Olympus is writing to inform you of a Field Corrective Action pertaining to the Everest Bipolar Cutting Forceps, *EG3005 &* EG3006-020. 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 devices with the affected batch numbers.
3. Please contact Olympus at XXXXX. 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. 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 them this notification.

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

Olympus requests that you report any complaints, including any package damage or signs of sterility breach, to [local facility complaint reporting contact]. [If applicable:] Adverse events experienced with the use of this product may also be reported [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 FY25-EMEA-10-FY25-001 Broken Forceps Trays

Facility Name	
Facility Address	
Contact Name	
Additional Customer Requests	

Insert description of the product names and model numbers of the affected products

Model #	**Batch #**	**Date Shipped**	**Qty Shipped to your facility**	**Qty remaining in Stock**

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* by *XX.XX.XXXX*