March X, 2019
Olympus reference: QIL 151-012

URGENT FIELD SAFETY NOTICE

Attention: Surgical Risk Management Department

Model Name	Part No	Description	
Diego Elite Turbinate Blades	EGBB2000SA	Bipolar Blade, 2mm straight, standard, type A	All Lot Numbers
Diego Elite Malleable Blades	EGMM4000SS	Malleable, standard, monopolar, 4 mm, T/A	
Diego Elite Bipolar Blades	EGBB4000SS	Bipolar Blade, 4 mm straight, standard, serrated, ds	
	EGBB4000SC	Bipolar Blade, 4 mm straight, standard, serrated, closed	
	EGBB4040XS	Bipolar Blade, 4 mm, 40°, convex, serrated, ds	
	EGBB4040XC	Bipolar Blade, 4 mm, 40°, convex, serrated, T/A, closed	
	EGBB4040SS	Bipolar Blade, 4 mm, 40°, standard, serrated, ds	
	EGBB4040SC	Bipolar Blade, 4 mm 40°, standard, serrated, closed	
Diego Elite Monopolar Sinus	EGMB4000SS	Monopolar Blade, 4 mm, straight, standard, serrated, ds	

Dear Health Care Practitioner

Olympus has become aware of an issue that requires your attention. This Field Safety Notice pertains to the above-referenced Olympus energy blades ("blades") used with the Olympus Diego Elite Consoles ("Console"). Our records indicate that your facility has purchased one or more of the Diego Elite Consoles. The Diego Elite Console is part of a electrosurgical system intended for cutting, coagulation, drilling, debriding and removal of bone, and soft and hard tissue in general ear, nose and throat ("ENT"), Sinus, Rhinology, Nasopharyngeal/Laryngology and Head and Neck procedures.

Olympus received a number of non-injury-related complaints that has made Olympus aware of a possibility that under certain conditions the Consoles may inadvertently permit activation of the RF energy feature when used with the above identified blades.

This problem is associated with specific Consoles due to the software installed on these Consoles. These Consoles, when used in combination with the above identified blades, may present this problem.

If the inadvertent activation occurred

- while the blade end is not contacting the patient, the only consequence would be a delay in the procedure while a replacement device is selected
- while in contact with patient anatomy, a burn could occur at the point of contact

- while it is in contact with the extraocular muscle or optic nerve, vision impairment might occur

Therefore, Olympus determines the risk to be significant.

Accordingly, Olympus is requiring you to immediately suspend the use and return all affected energy blade inventory. You can continue to use your Console with other non-energy blades and burrs. The issue will be fixed by a future software update to the Console. After this necessary update the energy blades will be available for purchase again.

In an effort to maximize patient safety and mitigate any potential risk to patient health, Olympus is notifying users of this complaint and requires you to take the following action:

Advice on actions to be taken by the user:

a) Inspect your inventory for the referenced Olympus blades and immediately remove them from use.
b) Contact the Olympus Customer Care at XXX-XXX-XXXX. You will be provided with instructions on how to return the affected blades as well as getting a credit note.
c) Please note on the enclosed questionnaire that you have received this notification.
d) Send the completed questionnaire to your Olympus representative [XXX].
e) If you have further distributed this product, identify your customers, forward them this FSN including the attachments, and appropriately document your notification process.

It is important that we receive your completed questionnaire. Olympus will be contacting you to arrange for the update of your console(s) software.

Your National Competent Authority has been informed of this Field Safety Notice.

Olympus regrets any inconvenience caused and fully appreciates your prompt cooperation in addressing this situation. If you require additional information or on-site support, please do not hesitate to contact Olympus directly at (XXX) XXX-XXXX from Monday till Friday or by e-mail at XXX.

Sincerely,

[Signature]

REPLY FORM – QIL 151-012

OLYMPUS URGENT FIELD SAFETY NOTICE **RECALL OF VARIOUS OLYMPUS ENERGY BLADES – PART NO LISTED BELOW:**						
[Name & Address of Hospital/Medical Facility]						
[Dept/Attn]						
[**Date]**						
OLYMPUS Energy Blades affected Part No. (Please insert the quantities available in your facility in front of the Part No)						
Diego Elite Turbinate Blades		**EGBB2000SA**				
Diego Elite Malleable Blades		**EGMM4000SS**				
Diego Elite Bipolar Blades		**EGBB4000SS**		**EGBB4000SC**		**EGBB4040XS**
		EGBB4040XC		**EGBB4040SS**		**EGBB4040SC**
Diego Elite Monopolar Sinus		**EGMB4000SS**				

I herewith acknowledge the receipt of your Field Safety Corrective Action.
Further I confirm that I have discarded any existing inventory of the above referenced Olympus energy blades and understood to contact the Olympus Customer Service in order to be provided with instructions on how to return the amount of above indicated affected.

I transferred the content of the attached FSN to all affected departments on which this action has an impact.

Name (Signature) _____

Name (Print) _____

Position _____

Please fax this completed reply form to Olympus at [contact number] latest by XXXX