Date: 12.03.2024

Olympus reference: QIL FY24-EMEA-40-FY24-OMSC-36-KD-645L

URGENT FIELD SAFETY NOTICE

RE: OLYMPUS Triangle Tip Electrosurgical Knives

Attention: Operating Room Director, Endoscopy Department, Gastroenterology Department

Material ID	Model Number	Material Description	Lot Numbers	UDI
N5412530	KD-645L	KD-645L TTKnife J 1pc dispo	All	
N2119630	KD-640L	KD-640L TTknife 1pc dispo. ESD	All	

Dear HealthCare Provider:

Olympus is writing to inform you of an increase in complaints for the triangle tip of the KD-640L and KD-645L Triangle Tip Electrosurgical Knives breaking off during use. The Triangle Tip Electrosurgical Knives are single-use and are designed to be used with Olympus endoscopes and electrosurgical units. The KD-640L knife is intended to cut tissue using high-frequency current within the upper digestive tract. The KD-645L knife is intended to cut and coagulate tissue using high-frequency current and flushing devices for submucosal injection within the digestive tract.

Olympus's investigation has identified that deterioration of the cutting knife can contribute to tip breakage during use. Deterioration, including overheating and burning, may occur due to use with non-Olympus electrosurgical units and/or use of output settings that exceed the specifications. Olympus is issuing this letter to remind users to utilize these devices in accordance with the Instructions for Use (IFU), which details critical Specifications regarding electrosurgical unit compatibility and output. The Specifications are found in IFU. For your convenience Rated high-frequency voltage specifications and relevant Warnings and Cautions for both devices are included below.

KD-640L	KD-645L
WARNING Use this instrument and A cord only in combination with products recommended by Olympus. If combined with products not recommended by Olympus, patient injury caused by increase in patient leakage current,operator injury, malfunction or equipment damage may result.	**WARNING** Use this instrument only in combination with products recommended by Olympus. If combined with products not recommended by Olympus, patient injury caused by increase in patient leakage current, operator injury, malfunction or equipment damage may result.
CAUTION Do not use this instrument and A cord in an output higher than the rated high-frequency voltage in the table on page 5. This could cause patient, operator	**CAUTION** Do not use this instrument in an output higher than the rated high-frequency voltage in the table on page 4. This could cause patient, operator, or assistant injury, such as

KD-640L	KD-645L
or assistant injury, such as thermal injury. It could also damage the endoscope, instrument and/or A cord. **Rated high-frequency voltage:** Cut: 1600 Vp (3200 Vp-p); COAG: 2900 Vp (5800 Vp-p)	thermal injury. It could also damage the endoscope, instrument. **Rated high-frequency voltage:** 4300Vp (8600Vp-p)

Olympus is sending this reminder after receiving thirteen (13) complaints for this issue associated with both non-Olympus electrosurgical units and high energy settings reported between February 2016 and January 2024, of which six (6) described serious injuries and two (2) described malfunctions.

Risk To Health

Use of devices or settings that are inconsistent with the specifications listed in the IFU may lead to patient harms such as device fragments breaking off into patient resulting in unexpected imaging or additional procedures/surgery for foreign body retrieval and/or prolonged surgery related these additional interventions and device replacement. Additional harms may include burns, perforation, foreign body reaction if device tip is unable to be located inside the patient, and possible aspiration for procedures done in the area of the hypopharynx.

Action Steps:

1. Carefully read the content of this Field Safety Notice.
2. Follow your facility's procedures for communication and handling of Field Safety Notices. Ensure all personnel, including clinical staff, are informed of the contents of this letter and the Instructions for Use. You may add a copy of this letter with your IFU.
3. Indicate on the Reply Form that you have received and understood this Field Safety Notice by filling out and returning the completed enclosed Reply Form back to your local Olympus representative latest by 05.04.2024.
4. If you have distributed these devices outside your facility, please notify your customers of this matter immediately by forwarding them this Field Safety Notice. Please appropriately document your notification process and let us know the end-customer feedback accordingly.

Olympus requests you to report any complaints, including any injuries associated with Triangle Tip Electrosurgical knife tip breakage, to concerns@olympus.co.uk.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact me directly at **ra@olympus.co.uk.**

Sincerely,

Charlotte Bell

Charlotte Bell
FSCA & QA Projects Lead – Region UI

REPLY FORM – QIL FY24-EMEA-40-FY24-OMSC-36-KD-645L

OLYMPUS URGENT FIELD SAFETY NOTICE **OLYMPUS Triangle Tip Electrosurgical Knives**
[Name & Address of Hospital/Medical Facility] **Customer Number**: 1046709
[Dept/Attn]
[**Date]**

I herewith acknowledge the receipt of your Field Safety Notice.
Further I confirm that I have transferred the content of the attached FSN to all affected departments on which this action has an impact. I understand the necessity of following the instructions carefully.

Name (Signature) _____

Name (Print) _____

Position _____

Please send your completed paper form response to OlympusFY24-40@Sedgwick.com latest by 5 April 2024.