March 1, 2024

MEDICAL DEVICE SAFETY REMINDER

OLYMPUS Triangle Tip Electrosurgical Knives
Models: KD-640L, KD-645L
Lot Numbers: All lot numbers
UDI-DI: KD-640L – 04953170208423; KD-645L - 04953170407857

Attention: Endoscopy Department, Operating Room Director, Risk Management

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' 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 Section 8. For your convenience the 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. **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 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)	**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 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 thermal injury. It could also damage the endoscope, instrument. **Rated high-frequency voltage:** 4300Vp (8600Vp-p)

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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. 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.
2. 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: “0443”
    c. Complete the form as instructed.
3. If you have distributed these devices outside your facility, please provide a copy of this letter to those facilities immediately.

Olympus requests you to report any complaints, including any injuries associated with Triangle Tip Electrosurgical knife tip breakage, the Olympus Technical Assistance Center at 1-800-848-9024, option 1. Adverse events experienced with the use of this product may also be reported to the Food and Drug Administration 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 at 647-999-3203 or Cynthia.Ow@Olympus.com.

Sincerely,

Cynthia Ow

Cynthia Ow
Field Corrective Actions Lead, Americas