Date: 08/01/2026
Olympus reference: QIL FY26-EMEA-17-FY25-009-A Thunderbeat Probe Fracture and Tissue Pad Detachment

URGENT FIELD SAFETY NOTICE

RE: THUNDERBEAT™ Hand Instrument
Attention: Operating room/ Surgery Department, Risk Management Department

Material ID	Model Number	Material Description	Lot Numbers	UDI-DI
EGTB-0545FCS	TB-0545FCS	Thunderbeat, 5MM, 45CM, Front-actuated Grip Type S	All lots distributed prior to December 2025	04953170383533
N5423330				04953170383519
N5423430				04953170383526
EGTB-0535FCS	TB-0535FCS	Thunderbeat, 5MM, 35CM, Front-actuated Grip Type S		04953170383564
N5423630				04953170383540
N5423730				04953170383557
EGTB-0520FCS	TB-0520FCS	Thunderbeat, 5MM, 20CM, Front-actuated Grip Type S		04953170383595
N5423930				04953170383571
N5424030				04953170383588
N3810430	TB-0535PC	Thunderbeat, 5MM, 35CM, Pistol Grip		04953170308659
N3810730	TB-0520IC	Thunderbeat, 5MM, 20CM, Inline Grip		04953170308710
N3810830	TB-0510IC	Thunderbeat, 5MM, 10CM, Inline Grip		04953170308734

This product removal replaces and supersedes the previous advisory FSN.
Our records indicate that your organization has purchased or received affected THUNDERBEAT™ hand instrument(s).
Immediately cease use of the affected devices and quarantine the products.

Dear HealthCare Provider:

The purpose of this letter is to inform you that Olympus is issuing a Product Removal Action for THUNDERBEAT™ Hand instruments (listed in the table above). This action is being taken due to ongoing complaints and reports for THUNDERBEAT™ Type S Hand instruments regarding:

- **Probe tip damage or breakage** - Multiple instances where probe tips of THUNDERBEAT™ Type S hand instruments have become damaged or broken during use (reference example in Figure 1).
- **Tissue pad issues** - Reports of tissue pad damage or detachment from the instruments (reference example in Figure 2).

Background

Olympus issued an advisory Field Safety Notice (FSN) in December 2024 regarding the THUNDERBEAT™ Type S Hand instruments (models TB-0535FCS, TB-0545FCS and TB-0520FCS) which reinforced the existing instructions and warnings from the product Instructions for Use (IFU) and emphasized that probe tip and/or tissue pad damage could occur if the IFU is not followed correctly.

Since the release of the advisory FSN, Olympus has continued to receive complaints in relation to this issue, and as a result, is issuing a **Product Removal action** for these devices. Between 2020 and 2025, Olympus received 4624 complaints globally, including 1 reported death, 403 serious injuries and 2580 malfunctions. In addition, Olympus has identified additional THUNDERBEAT™ hand instrument models which are impacted due to similar probe design. Therefore, to exercise further caution, these models are also being removed from the market (refer to the table above for the full list of impacted devices).

THUNDERBEAT™ hand instruments are intended to be used for open, laparoscopic, and endoscopic surgery to cut, seal, coagulate, grasp, and dissect. They are sterile, single-use instruments which are intended to be used with the Ultrasonic Generator (USG-400), Ultrasonic Bipolar Generator (USG-410), the Electrosurgical Generator (ESG-410) and the THUNDERBEAT™ Transducer, (TD-TB400).

Reason for Action:

Olympus was made aware, via customer complaints, of reports where probe tips of THUNDERBEAT™ hand instruments are becoming damaged or are breaking (reference example in Figure 1), as well as instances of tissue pad damage or detachment (reference example in Figure 2). Investigations by Olympus demonstrated that these issues can occur when the instructions and warnings in the IFU are not followed, specifically, taking very large bites of tissue, contact with metal while activating, and activation without tissue between the jaws. However, due to a continuation of occurrences of this issue, Olympus is removing potentially affected models of THUNDERBEAT™ hand instruments from the market.

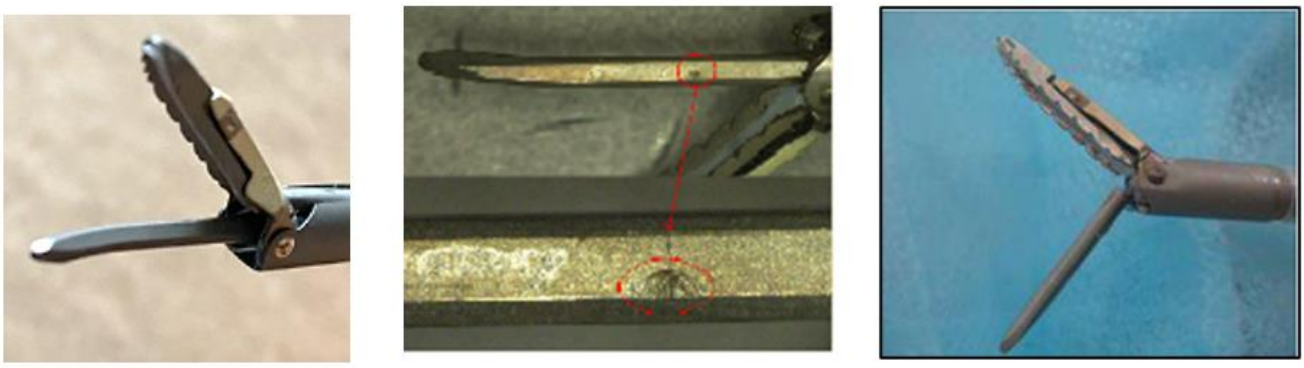

Figure 1. Example of Thunderbeat Probe in accordance with specifications (left), Cracked Probe (Center) and Probe Fracture (right)

Figure 2. Example of Thunderbeat Probe in accordance with specifications (Left), Tissue Pad Deformation (Center), Tissue Pad Detachment (Right)

Risk to Health:

A broken probe tip or a damaged tissue pad may lead to various patient harms. Of these harms, the most common harm is a foreign body in the patient due to a probe tip and/or tissue pad that becomes damaged and breaks off the device during use. When this occurs, this can also potentially result in a prolonged operative time, the requirement to perform imaging examinations, or an additional surgical procedure to locate and remove the broken device fragment. In rare circumstances, tissue damage could occur due to exposed sharp edges on the device when the probe tip breaks or becomes damaged. Additionally, bleeding may occur if the tissue pad fails or probe breaks, causing an inadequate seal. Post-operative bleeding events could, in rare circumstances, result in life-threatening injuries. Olympus has received one complaint of a postoperative death due to hemorrhage; however, the device was not returned to Olympus for further evaluation and there was insufficient information in the reported complaint details provided to Olympus to conclude the hemorrhage was causally related to probe tip or tissue pad damage.

The potential harms of burn(s), granuloma, and inflammatory reaction may also result due to a broken probe tip or tissue pad that is not immediately retrieved and/or is unretrievable. While not seen in the complaint data, these harms may occur on rare occasions. The potential harm of burn(s) may occur due to retained heat in the probe tip or tissue pad that potentially breaks off into a patient.

Actions Required:

Olympus requires you to take the following actions:

1. Examine your inventory for affected Thunderbeat hand instrument models as listed on page 1 of this FSN.
2. **Immediately cease use of all affected devices and quarantine the products.**
3. If you have affected products in your inventory, please contact Olympus with regard to return of affected products. Olympus will issue a credit to your facility upon return of your affected product
4. Olympus requests that you acknowledge receipt of this FSN.
5. If you have further distributed THUNDERBEAT™ devices, please identify your customers and forward this notice to them immediately.

The Medicines and Healthcare Products Regulatory Agency (MHRA) is aware of the actions described in this letter.

Olympus requests that you report any complaints, including probe damage or pad detachment to concerns@olympus.co.uk. Adverse events experienced with the use of this product may also be reported to the Medicines and Healthcare Products Regulatory Agency (MHRA) online.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact charlotte.bell@olympus.com or Olympus directly at 01702 616333 from Monday through Friday or by e-mail at ra@olympus.co.uk.

Sincerely,

Charlotte Bell

Field Safety Corrective Actions & Quality Assurance Projects Manager

REPLY FORM

QIL FY26-EMEA-17-FY25-009-A Thunderbeat Probe Fracture and Tissue Pad Detachment

Facility name	
Facility Address	
Contact Name	
Contact E-mail Address	
Contact Telephone Number	

Insert description of the product names, lot numbers and quantity of the affected products remaining in your facility

Catalogue Number	Lot Number	Quantity

I acknowledge receipt of this notification. I confirm that I have further communicated 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 ra@olympus.co.uk by date 02/02/2026.