

Reference: 2025-X003M

17 December 2025

URGENT: MEDICAL DEVICE REMOVAL

Product: OLYMPUS Thunderbeat Hand Instruments

Product Name	Model/Catalog Number	Lot Numbers
THUNDERBEAT™, 5MM, 45CM, Front-actuated Grip Type S	TB-0545FCS	All lots
THUNDERBEAT™, 5MM, 35CM, Front-actuated Grip Type S	TB-0535FCS	
THUNDERBEAT™, 5MM, 20CM, Front-actuated Grip Type S	TB-0520FCS	
THUNDERBEAT™, 5MM, 45CM, Front-actuated Grip	TB-0545FC	
THUNDERBEAT™, 5MM, 35CM, Front-actuated Grip	TB-0535FC	
THUNDERBEAT™, 5MM, 20CM, Front-actuated Grip	TB-0520FC	
THUNDERBEAT™, 5MM, 10CM, Inline Grip	TB-0510IC	
THUNDERBEAT™, 5MM, 20CM, Inline Grip	TB-0520IC	

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.

Attention: **Operating Rooms/Surgery Departments, Risk Management Department**

Dear Healthcare Professional,

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.

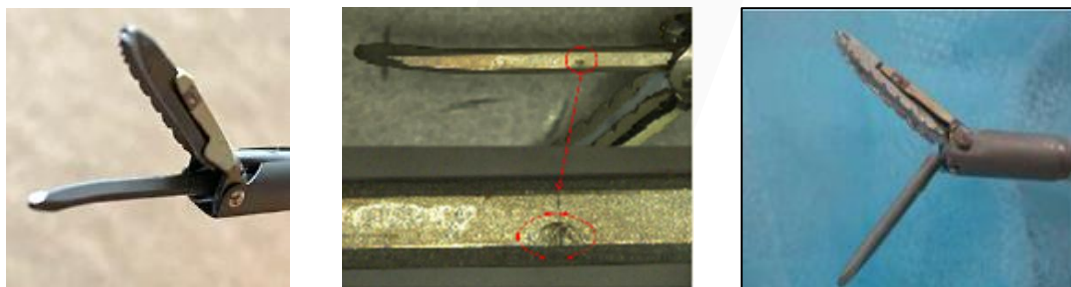


Figure 1. Example of THUNDERBEAT™ Probe in accordance with specifications (left), Cracked Probe (Center) and Probe Fracture (right)



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 casually 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.

Action Required:

Our records indicate that your facility has received one or more of the affected devices. **Olympus requests 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. Olympus will contact you to arrange for return of your device to Olympus, and we will issue a credit to your facility.
4. Olympus requests that you acknowledge receipt of this letter. Indicate on the Response Form that you have received and understood this notification by filling out and returning the completed enclosed Response Form to us.
5. Please forward this notice immediately to other users who may have the THUNDERBEAT™ devices if you have further distributed it.

Olympus requests that you report complaints, including probe damage or tissue pad detachment and adverse events experienced with the use of this product to Olympus.

Olympus regrets any inconvenience caused and fully appreciates your prompt cooperation in addressing this matter. If you have any questions or concerns, please do not hesitate to contact us for additional information.

Contact for enquiries

Regulatory Affairs and Quality Assurance Department

Email : mes-ra.oml@olympus.com

Tel : (603) 7650 8990

Fax : (603) 7650 8999

The **Medical Device Authority** has been informed of this notice.

Yours sincerely,

Hideki Nagai

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Hideki Nagai

Managing Director

Olympus (Malaysia) Sdn. Bhd

RESPONSE FORM

Medical Device Recall - Acknowledgement and Receipt

Response is required

[Name & Address of Hospital/Medical Facility]
[Dept/Attn]

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Please distribute this information to the appropriate personnel at your facility, including surgeons who may have received the product which is the subject of this recall notice.

I have read and understand the recall instructions provided in the **17 December 2025** letter.

Yes No

Any adverse incidents associated with recalled product?

Yes No

If yes, please explain: _____

Check the applicable boxes below:

- I DO NOT have affected device remaining. All have been used or discarded.
- I DO have the affected device, which I will return to Olympus.

Lot Number: _____ Quantity to be Returned (UOM): _____

Name: _____

Designation: _____

.....
Signature & Company Stamp

.....
Date

Please send the completed and signed Response Form to Regulatory Affairs and Quality Assurance Department to
[Fax/Email : (603) 7650 8999 / mes-ra.oml@olympus.com]






2025-X003M Recall - Customer Letter

Final Audit Report

2025-12-17

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