

**URGENT: MEDICAL DEVICE PRODUCT REMOVAL**

**THUNDERBEAT Hand Instruments**

Product Name	Model/Catalog Number	Lot Numbers	UDI-DI
THUNDERBEAT, 5MM, 45CM, Front-actuated Grip Type S	TB-0545FCS	All products distributed prior to December 22, 2025	4953170383519 4953170383533 4953170383526 4953170409684
THUNDERBEAT, 5MM, 35CM, Front-actuated Grip Type S	TB-0535FCS		4953170383540 4953170383564 4953170383557 4953170409677
THUNDERBEAT, 5MM, 20CM, Front-actuated Grip Type S	TB-0520FCS		4953170383571 4953170383595 4953170383588
THUNDERBEAT, 5MM, 45CM, Front-actuated Grip	TB-0545FC		4953170464966
THUNDERBEAT, 5MM, 35CM, Front-actuated Grip	TB-0535FC		4953170464959
THUNDERBEAT, 5MM, 20CM, Front-actuated Grip	TB-0520FC		4953170370502 4953170464942
THUNDERBEAT, 5MM, 45CM, Pistol Grip	TB-0545PC		4953170308635
THUNDERBEAT, 5MM, 35CM, Pistol Grip	TB-0535PC		4953170308536 4953170308659
THUNDERBEAT, 5MM, 45CM, Inline Grip	TB-0545IC		4953170308673 4953170464980
THUNDERBEAT, 5MM, 35CM, Inline Grip	TB-0535IC		4953170464973
THUNDERBEAT, 5MM, 20CM, Inline Grip	TB-0520IC		4953170308581 4953170308710
THUNDERBEAT, 5MM, 10CM, Inline Grip	TB-0510IC		4953170308734

**This Product Removal Notice replaces and supersedes the previous Field Safety Notice.** 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.**

Date: 22-DEC-2025

**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 Type S Hand instruments (listed in the table above). This action is being taken due to ongoing complaints and reports regarding:

- **Probe tip damage or breakage** - Multiple instances where probe tips of THUNDERBEAT 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.

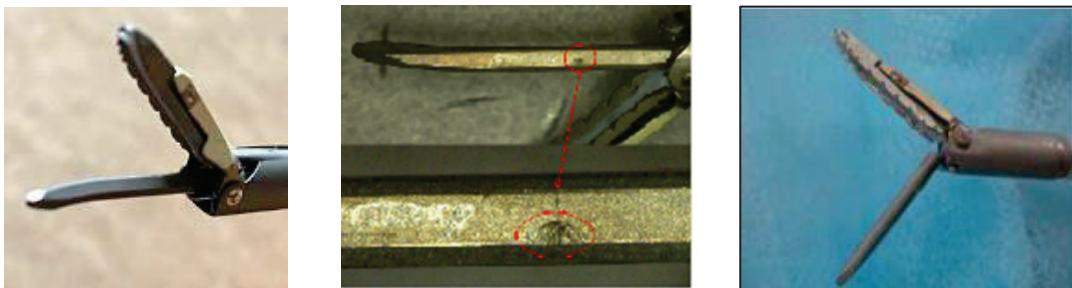


Figure 1. Example of THUNDERBEAT Probe in accordance with specifications (left), Cracked Probe (Center) and Probe Fracture (right)



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.

**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. Contact Customer Service at 1-800-848-9024, option 2, to obtain a Return Material Authorization. Olympus will issue a credit to your facility upon return of your affected product.
4. Olympus requests that you acknowledge receipt of this FSN through our web portal:
  - a. Go to <https://olympusamerica.com/recall>
  - b. Enter the recall number "0483"
  - c. Complete the form as instructed.
5. If you have further distributed THUNDERBEAT devices, please identify your customers and forward this notice to them immediately.

Olympus requests that you report any complaints, including probe damage or pad detachment, to Technical Assistance Center (TAC) at 1- 800-848-9024 (option 1), and the FDA. Adverse events experienced with the use of this product may also be reported to the FDA's 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 by phone at (647) 999-3203 or by e-mail at [Cynthia.Ow@Olympus.com](mailto:Cynthia.Ow@Olympus.com).

Sincerely,

*Cynthia Ow*

Cynthia Ow

Sr. Manager, Field Corrective Action, Americas