Reference: 2024-009M

17 December 2024

URGENT - FIELD SAFETY NOTICE

To user of **Olympus Thunderbeat Type S Hand Instruments**

Product Name:

Product Name	Model/Catalog Number	Serial/Lot(s)
Thunderbeat, 5MM, 35CM, Front-actuated Grip Type S	TB-0535FCS	All (unexpired)
Thunderbeat, 5MM, 45CM, Front-actuated Grip Type S	TB-0545FCS	All (unexpired)
Thunderbeat, 5MM, 20CM, Front-actuated Grip Type S	TB-0520FCS	All (unexpired)

Re: Olympus to Reinforce Existing Instructions and Warnings from IFU for Thunderbeat Type S Hand Instrument.

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

Dear Healthcare Professional,

Olympus is issuing a Field Safety Notice (FSN) to reiterate and reinforce the existing instructions and warnings from the Instructions for Use (IFU) for the above listed THUNDERBEAT Type S Hand instruments. Our records indicate that your organization has a THUNDERBEAT Type S Hand instrument in your possession and therefore may be impacted by this FSN. The THUNDERBEAT Type S Hand instruments are sterile, single use instruments and 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 has been made aware, via customer feedback, of reports where probe tips of the THUNDERBEAT Type S Hand instrument are becoming damaged or are breaking (Reference example in Figure 1), as well as instances of pad damage or detachment (Reference example in Figure 2). 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.

During use, if the device probe breaks or there is significant tissue pad damage, an audible alarm tone will be generated, and an error will be visibly displayed on the generator. Follow the steps on the screen and in the IFU associated with the error message. For probe damage and ultrasonic instrument damage related errors, per the IFU, immediately interrupt the procedure and replace the instrument. Even if the damage cannot be confirmed visually, do not attempt to reuse the instrument. A very fine, invisible crack may develop into a detached instrument tip. Not replacing the instrument per the IFU can cause probe damage/breakage and pad damage/detachment, which can result in patient harm.

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Unit T2-L05-1, PJ33, No. 3, Jalan Professor Khoo Kay Kim, Section 13, 46200 Petaling Jaya, Selangor, Malaysia
Tel: (603) 7650 8990 Fax: (603) 7650 8999

Therefore, the purpose of this FSN is to reiterate the importance of these instructions and warnings to reduce occurrences of probe damage/breakage and pad damage/detachment. Please refer to Appendix 1 for excerpts from the IFU highlighting specifics around the warnings, errors and scenarios which can lead to these issues. Refer to the relevant IFU for the full content of the Instructions, Warnings, and Cautions to be followed.

In addition, Olympus strongly recommends the use of the ITM (Intelligent Tissue Monitoring) function to prevent probe pad damage due to over-activation and therefore reduce the likelihood of probe tip damage. When using this function, the energy output automatically stops after the target tissue is divided. This is indicated by an audible signal/stop tone. Note: This function may need to be switched to 'on' on your generator, if not already enabled.

Customers can also access in-service training to support the correct use of the device by contacting your local Olympus representative (Reference Actions Required below).

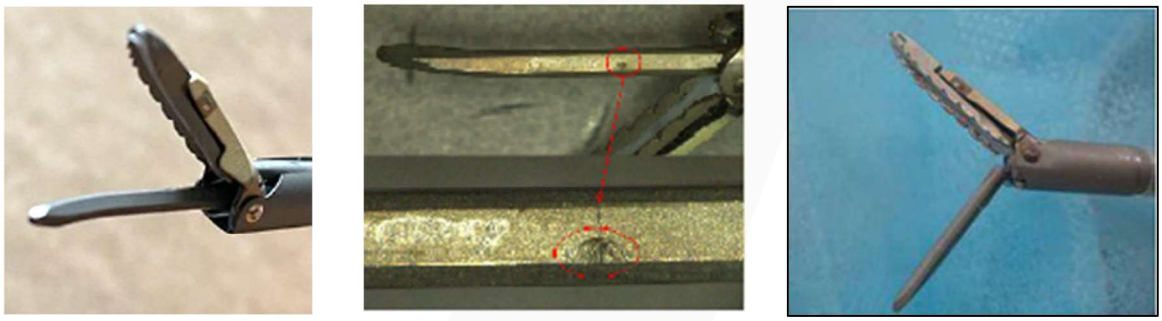

Figure 1. Example of Thunderbeat Probe in accordance with specifications (left), Cracked Probe (Center) and Probe Fracture (right)

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 damaged tissue pad may lead to patient harms of foreign body in the patient, requiring imaging and prolonged operative time or an additional procedure to locate and remove the broken piece. Additionally, tissue damage and bleeding could occur due to exposed sharp edges. A broken piece remaining in the patient could potentially lead to an inflammatory reaction or granuloma. The probe tip or tissue pad breaking due to high temperatures and falling into the patient, may cause thermal injury to the patient.

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Actions Required:
Our records indicate that your facility has one or more of the affected products. Olympus requires you to take the following actions:

1. Carefully read the content of this FSN.
2. Ensure all personnel are completely knowledgeable and thoroughly trained on the content of this FSN and the relevant IFU.
3. If you have further distributed this product, identify your customer's, and forward them this notification.
4. Olympus request that you acknowledge receipt of this FSN, by:
    a. Indicating on the enclosed Response Form if you would like to receive in-service training to support the correct use of this device.
    b. Demonstrating that you have received and understood this notification by completing all available fields in the Reply Form and returning it back to your local Olympus representative latest by 20th June 2025.

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

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact us.

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
……
Hideki Nagai
Managing Director
Olympus (Malaysia) Sdn. Bhd.

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Response Form

Please send the complete and signed Response Form to Regulatory Affairs and Quality Assurance Department at:

To : Olympus (Malaysia) Sdn. Bhd, Regulatory Affairs & Quality Assurance
Fax/Email : (603) 7650 8999 / mes-ra.oml@olympus.com
From : _____ [Facility Name] Contact no.:_____
Date : _____
Ref : 2024-009M

URGENT - FIELD SAFETY NOTICE

Re: Olympus to Reinforce Existing Instructions and Warnings from IFU for Thunderbeat Type S Hand Instrument.

I acknowledge receipt of the Field Safety Notice ("FSN") referenced above. I confirm that I have further communicated to any affected departments.

Check the applicable boxes below:

☐ Would like to receive in-service training to support the correct use of this device.

☐ I DO NOT have affected product remaining. Product has been condemned or discarded.

☐ I DO have the affected product, which I will adhere to the Existing Instructions and Warnings from IFU.

Additional Customer Requests:

(Indicate if you have any additional requests to support this action)

Name: _____

Designation: _____

....

Signature & Company Stamp Date

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Appendix 1

1) **Subset of Warnings on Avoiding Misuse (Refer to IFU for complete Instructions, Warnings, Cautions, etc.)**

WARNING

- …. Do not activate output while grasping hard tissue such as bone or highly calcified tissue, or hard objects such as metal clips, stapler, or other instruments (e.g., uterine manipulator, forceps, and others). Otherwise, it may cause … tear/deforming/splitting/protruding/partial separating of the tissue pad. In turn, the probe may break...

- Do not activate output while applying the probe tip to the tissue with a strong force, grasping thick tissue, positioning the tissue, twisting the shaft, or rotating the rotation knob... Otherwise, it may cause the deforming/splitting/protruding of tissue pad or a scratch on the probe tip by interference with the other parts, which could result in the probe tip breaking and falling off inside the body cavity.

- During the treatment, do not activate output while applying the probe tip to the tissue with a strong force, grasping thick tissue, or twisting the handle…. Otherwise, the probe tip and/or grasping section may be damaged, which may result in falling of the probe tip and/or tissue pad.

- During colpotomy and/or amputation, avoid inserting the probe tip vertically and deeply into the uterine cervix, and activating the THUNDERBEAT instrument. Do not overfill the grasping section with a large bite of tissue. This may result in damage to the probe tip.

2) **ITM (Intelligent Tissue Monitoring) Function Recommendation**

Olympus strongly recommends the use of the ITM (Intelligent Tissue Monitoring) function to prevent probe pad damage due to over-activation and therefore reduce the likelihood of probe tip damage. When using this function, the energy output automatically stops after the target tissue is divided. This is indicated by an audible signal/stop tone. Note: This function may need to be switched to 'on' on your generator, if not already enabled.

Additional IFU information to be followed:
Once a part of living tissue is divided, stop the output immediately regardless of absence of the stop tone. Otherwise, the THUNDERBEAT/SONICBEAT instrument may be damaged.

3) **Probe Tip Damage Error**

Example triggers: *Cracked probe, ultrasonic resonance failure.*

- **When using USG-400 or USG410 Ultrasonic Generator: Error displayed: "U504 Probe Damage Error"**
- **When using ESG-410 Electrosurgical Generator: Error displayed: "E1765 Damaged Ultrasonic Instrument"**

Key points from IFU to be followed (exact verbiage may differ by Generator):

- If the electrosurgical generator detects a damaged instrument this is indicated by the error message "Probe Damage Error" or "Damaged Ultrasonic Instrument". The energy output is automatically stopped.
- Immediately interrupt the procedure.
- When the error message is displayed on the screen, stop using the instrument and withdraw it from the body cavity.

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- Do not perform an activation test with the instrument.
- ● Check if the instrument tip is still attached. If the tip has fallen into the patient's body cavity, ensure to withdraw the tip from the patient.
  ● Even if the damage cannot be confirmed visually, do not attempt to reuse the instrument. A very fine, invisible crack may develop into a detached instrument tip.
  ● Replace the instrument as instructed by the error message.

  Do not turn off the ultrasonic generator or disconnect the transducer plug from the transducer socket of the ultrasonic generator (before replacement).

4) <u>Seal and Cut Short Circuit Error</u>

Example triggers: *Metallic object grasped during activation, grasping section wear, activated in body fluid.*

- **When using <u>USG-400 Ultrasonic Generator</u>: Error displayed: "U508 SEAL & CUT Short circuit error" or "U511 SEAL short circuit error"**
- **When using <u>ESG-410 Electrosurgical Generator</u>: Error displayed: "E2862 Short circuit" or "E2863 Short circuit"**

Key points from IFU to be followed (exact verbiage may differ by Generator):
● Confirm that no metal object is grasped between jaw and prove tip, then confirm activation.
● Remove tissue and fluids from the surface of the insertion tube, probe distal end, and grasping section of the device.
● If the error window is still displayed, replace the THUNDERBEAT or SONICBEAT instrument.

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2024-009M FSN

Final Audit Report 2024-12-17

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