

## URGENT FIELD SAFETY NOTICE

**Product: Thunderbeat, 5MM, 35CM, Front-actuated Grip Type S / TB-0535FCS  
Thunderbeat, 5MM, 45CM, Front-actuated Grip Type S / TB-0545FCS  
Recall of certain lot numbers (please refer to Attachment 1)  
Attention: Surgery Department, Risk Management Department**

| Material ID  | Model      | Name   | UDI           |
|--------------|------------|--|---------------|
| EGTB-0535FCS | TB-0535FCS | Thunderbeat, 5MM, 35CM, Front-actuated Grip Type S | 4953170409677 |
| EGTB-0545FCS | TB-0545FCS | Thunderbeat, 5MM, 45CM, Front-actuated Grip Type S | 4953170409684 |

Dear Healthcare Professional:

Olympus has become aware of a matter that may require your attention. This recall pertains to certain lots of the above-referenced Olympus Thunderbeat models and our records indicate that your facility has purchased one or more of the affected lots.

The THUNDERBEAT Type S hand instruments are indicated for open, laparoscopic (including single-site surgery) general surgery and gynecological surgery (including urologic, thoracic, plastic and reconstructive, bowel resections, cholecystectomies, Nissen fundoplication, adhesiolysis, oophorectomy, hysterectomies (both vaginal assisted and abdominal) etc.) and endoscopic surgery or in any procedure in which cutting, vessel ligation (sealing and cutting), coagulation, grasping, and dissection is performed. These devices have been designed to seal and cut vessels (up to and including 7 mm in diameter), tissue bundles, and lymphatics.

Olympus is taking this recall action after discovering that the Thunderbeat's blue seal button may remain in the engaged position after the button is released and not immediately return to a neutral position. Olympus is requesting healthcare facilities return the model and lot numbers subject to this recall.

The blue seal button activates the Thunderbeat's seal function for tissue and vessel sealing but does not activate a cutting function. This issue has only been observed on the Blue Seal button when it is activated from the right side and NOT when activated via the center or left side. In addition, this is limited to the Blue Seal button and not the Purple Seal & Cut button. Both buttons are designed to be momentary contact switches that are only active when depressed.

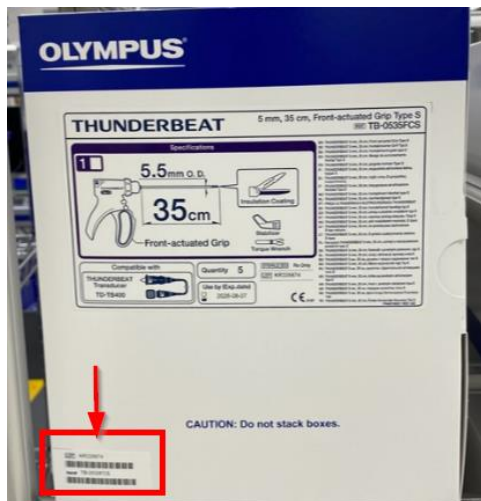
### **Risk to Patient Health:**

The potential risk associated with a sticky Thunderbeat seal button is continued activation of bipolar energy beyond the intended stop point, which in rare occasions may cause unintended tissue burns. Additionally, potential procedure delay could occur should the clinician choose to replace the Thunderbeat device.

## Action steps to be taken by the end user:

Our records indicate that your facility has purchased one or more Thunderbeat devices. Olympus requests you to take the following actions:

1. Carefully read the content of this Field Safety Notice (FSN).
2. Ensure all personnel are completely knowledgeable and thoroughly trained on the content of this FSN.
3. Inspect your inventory and identify any Thunderbeat models and lots subject to this action. Please refer to the Attachment 1 for the identification of the affected lots. Please check all areas of the hospital to determine if any of these devices remain in inventory. The lot number can be found on the box or pouch as illustrated below:



Location of Lot Number on Box



Location of Lot Number on Pouch

4. **Cease use of any affected product and quarantine any affected product.**
5. Contact your Olympus customer service representative by [Regional contact]. Olympus will issue a Return Material Authorization to return any affected product at no charge. Olympus will issue a credit to your facility upon return of affected product.
6. If you have distributed these devices outside your facility, please notify your customers of this matter immediately by forwarding them this Field Safety Notice. Please appropriately document your notification process and let us know the end-customer feedback accordingly.
7. Indicate on the Reply Form that you have received and understood this Field Safety Notice by filling out and returning the completed enclosed Reply Form back to your local Olympus representative latest by 10.10.2023.

**Your National Competent Authority** is aware of the actions described in this letter. Olympus requests that you report complaints to **[Regional Complaint Intake Contact]**. **[Region to include as applicable]** Adverse events experienced with the use of this product

may also be reported to **[Regional to revise to local competent authority]** by **[competent authority contacts]**.

Sincerely,

A handwritten signature in black ink that reads "Charlotte Bell". The signature is written in a cursive, flowing style.

Charlotte Bell

FSCA & QA Projects Lead – Region UI

## Attachment 1: affected lot numbers

| Catalog Number | Lot Number |
|----------------|------------|
| TB-0535FCS     | KR314647   |
| TB-0535FCS     | KR314650   |
| TB-0535FCS     | KR314651   |
| TB-0535FCS     | KR314652   |
| TB-0535FCS     | KR314654   |
| TB-0535FCS     | KR314655   |
| TB-0535FCS     | KR314656   |
| TB-0535FCS     | KR314657   |
| TB-0535FCS     | KR314659   |
| TB-0535FCS     | KR314660   |
| TB-0535FCS     | KR314661   |
| TB-0535FCS     | KR314662   |
| TB-0535FCS     | KR314663   |
| TB-0535FCS     | KR314666   |
| TB-0535FCS     | KR314667   |
| TB-0535FCS     | KR314668   |
| TB-0535FCS     | KR314669   |
| TB-0535FCS     | KR314670   |
| TB-0535FCS     | KR314671   |
| TB-0535FCS     | KR314672   |
| TB-0535FCS     | KR314673   |
| TB-0535FCS     | KR314674   |
| TB-0535FCS     | KR314675   |
| TB-0535FCS     | KR314676   |
| TB-0535FCS     | KR314677   |
| TB-0535FCS     | KR314678   |
| TB-0535FCS     | KR314679   |
| TB-0535FCS     | KR316617   |
| TB-0535FCS     | KR316625   |
| TB-0535FCS     | KR316627   |
| TB-0535FCS     | KR316629   |
| TB-0535FCS     | KR316637   |
| TB-0535FCS     | KR316639   |
| TB-0535FCS     | KR316668   |

|            |          |
|------------|----------|
| TB-0535FCS | KR316682 |
| TB-0535FCS | KR316683 |
| TB-0535FCS | KR316685 |
| TB-0535FCS | KR319616 |
| TB-0535FCS | KR319626 |
| TB-0535FCS | KR319632 |
| TB-0535FCS | KR319639 |
| TB-0535FCS | KR319643 |
| TB-0535FCS | KR319648 |
| TB-0535FCS | KR319652 |
| TB-0535FCS | KR319655 |
| TB-0535FCS | KR319668 |
| TB-0535FCS | KR319676 |
| TB-0535FCS | KR332609 |
| TB-0535FCS | KR332615 |
| TB-0535FCS | KR332635 |
| TB-0535FCS | KR332643 |
| TB-0535FCS | KR335733 |
| TB-0535FCS | KR335738 |
| TB-0535FCS | KR335741 |
| TB-0535FCS | KR335749 |
| TB-0535FCS | KR335760 |
| TB-0535FCS | KR335776 |
| TB-0535FCS | KR335781 |
| TB-0535FCS | KR335784 |
| TB-0535FCS | KR335785 |
| TB-0535FCS | KR335786 |
| TB-0535FCS | KR335794 |
| TB-0535FCS | KR335796 |
| TB-0535FCS | PW308605 |
| TB-0535FCS | PW308606 |
| TB-0535FCS | PW308607 |
| TB-0535FCS | PW308608 |
| TB-0535FCS | PW308609 |
| TB-0535FCS | PW308610 |
| TB-0535FCS | PW308611 |
| TB-0535FCS | PW308613 |

|            |          |
|------------|----------|
| TB-0535FCS | PW308614 |
| TB-0535FCS | PW308615 |
| TB-0535FCS | PW308616 |
| TB-0535FCS | PW308663 |
| TB-0535FCS | PW308664 |
| TB-0535FCS | PW308665 |
| TB-0535FCS | PW308772 |
| TB-0535FCS | PW308773 |
| TB-0535FCS | PW308775 |
| TB-0535FCS | PW308776 |
| TB-0535FCS | PW308777 |
| TB-0535FCS | PW308786 |
| TB-0545FCS | KR313734 |
| TB-0545FCS | KR319658 |
| TB-0545FCS | KR326619 |

