Date: September XX, 2023
Olympus Reference: QIL FY24-EMEA-18-FY24-OMSC-24

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:

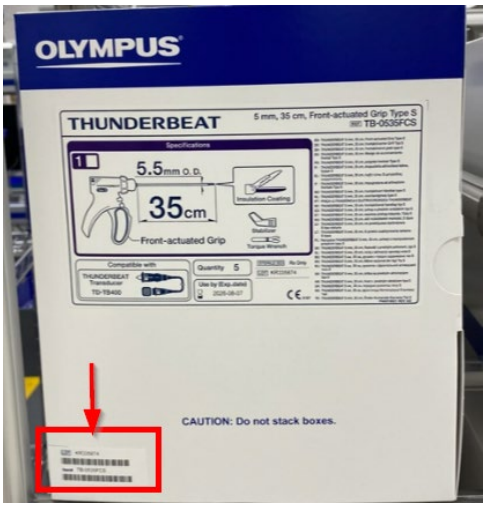
The potential risk associated with a sticky Thunderbeat seal button is continued activation of bipolar energy beyond the intended stop point, which in rare occasions may cause unintended tissue burns. Additionally, potential procedure delay could occur should the clinician choose to replace the Thunderbeat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

Action steps to be taken by the end user:

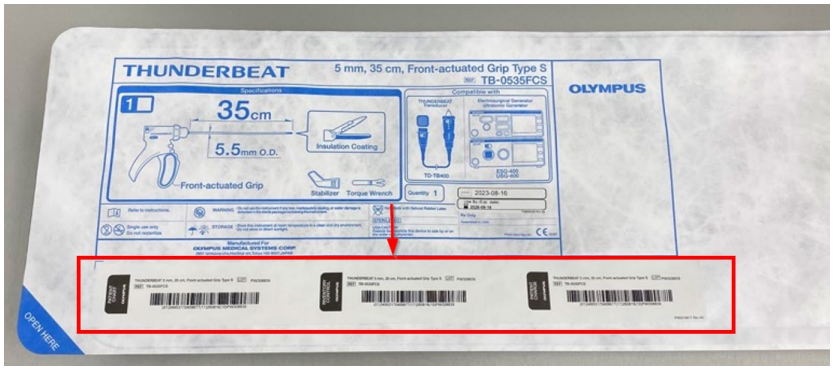
Our records indicate that your facility has purchased one or more Thunderbeat devices. Olympus requests you to take the following actions:

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 XX.XX.XXXX.

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,

[SIGNATORY]
[Contact Name]

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

REPLY FORM – QIL FY24-EMEA-18-FY24-OMSC-24

OLYMPUS URGENT FIELD SAFETY NOTICE
Market removal of certain lot numbers of
Thunderbeat, 5MM, 35CM, Front-actuated Grip Type S / TB-0535FCS and
Thunderbeat, 5MM, 45CM, Front-actuated Grip Type S / TB-0545FCS

[Name & Address of Hospital/Medical Facility]

[Dept/Attn]

[**Date]**

[**Inventory information]**

Model Name	Lot Numbers	Quantity

I herewith acknowledge the receipt of your Field Safety Notice.
Further I confirm that I have transferred the content of the attached FSN to all affected departments on which this action has an impact.

Name (Signature) _____

Name (Print) _____

Position _____

Please send your completed paper form response to XXXXX mailto:latest by XXXX.