

Date: 11 December 2015

URGENT: FIELD SAFETY NOTICE

Action Identifier Number: **210**

Type of Action: **Field Safety Notice**

Affected Products:

TB-0545PC Thunderbeat 5mm, 45cm, Pistol Grip
TB-0535PC Thunderbeat 5mm, 35cm, Pistol Grip
TB-0535IC Thunderbeat 5mm, 35cm, Inline Grip
TB-0520IC Thunderbeat 5mm, 20cm, Inline Grip
TB-0510IC Thunderbeat 5mm, 10cm, Inline Grip
TB-0545FC Thunderbeat 5mm, 45cm, Front-Actuated Grip
TB-0535FC Thunderbeat 5mm, 35cm, Front-Actuated Grip
TB-0920OE Thunderbeat Open Extended Jaw
TB-0009OF Thunderbeat Open Fine Jaw

Affected Serial Numbers: **All Serial Numbers**

Dear Customer,

Olympus is committed to ongoing support to our customers to ensure the safe and effective use of all of our medical devices.

THUNDERBEAT was launched into the UK market four years ago and we have seen rapid and continued uptake of these devices across the country in multiple specialties. To address customer training needs Olympus holds Professional Education events to help ensure that our customers remain satisfied with the product performance and operative outcomes.

If you require or would like further training on the device at your hospital please confirm on the Field Service Reply form attached.

Description of the Problem:

We are aware that when implementing and converting to new technologies there can be some subtle differences which take getting used to and as a result there have been some instances where the following has taken place:

- Partial separation of PTFE pad
- Premature wear of PTFE pad
- Hairline fracture of Ultrasonic probe

To date, we can confirm no patient injuries have been reported that can be attributed to product failures.

Actions to be taken by the end-user:

As part of our ongoing commitment to patient safety, we would like to remind you of the following for the safe and effective use of THUNDERBEAT:

- Should the Generator sound any error messages, or the device has abnormal noise, output, performance or appearance, or a malfunction be observed whilst in use, please stop and check the equipment according to the instructions for use.
- Improper use of the instrument may lead to premature wear, partial separation of the Teflon pad, probe breakage, or the probe tip falling off inside the body cavity, with or without patient injury. Please refer to the instructions for use in order to ensure proper use of the equipment.
- Please complete and return the attached reply form confirming receipt of this Field Safety Notice by **21 December 2015**.

For further information, please find a quick-reference guide for THUNDERBEAT enclosed that details selected information important for the safe and effective use of THUNDERBEAT. For complete instructions, please always refer to the instructions for use.

Transmission of the Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please transfer this notice to other organisations on which this action may have an impact.

Yours Sincerely,

ROBERT GRIGGS

General Manager – Quality Management and Regulatory Affairs

Robert.griggs@olympus.co.uk

Telephone Number: 01702452133 (direct)

01702616333 Ext52133

Enc. Reply

Date: 11 December 2015

URGENT: FIELD SAFETY NOTICE REPLY FORM

Please send the completed and signed reply form by email or fax to:

Mr Robert Griggs – General Manager – Quality Management and Regulatory Affairs

E-Mail: robert.griggs@olympus.co.uk

Fax: +44 (0) 1702 452133

Important Field Safety Notice information concerning;

THUNDERBEAT HANDPIECES

Dear Mr Griggs

We confirm receipt of your Field Safety Notice and enclosed quick reference guides. We confirm that we have communicated the content of this notification to all affected personnel.

We would like to request further onsite product training of the device and request the Territory Manager contact us to make arrangements. YES / NO

Name: _____

Hospital: _____

Department: _____

Address: _____

Postal Code/ City: _____

Signature

Date