

14 October 2013

Dear Olympus Distributor,

The following letter was sent to all Olympus THUNDERBEAT customers in the United States of America and Canada. The letter was copied to the US Food and Drugs Administration (FDA) and shortly appeared upon independent vigilance monitoring websites.

URGENT: Medical Device Field Corrective Action

Attention: Surgery Department
Risk Management Department

Re: OLYMPUS THUNDERBEAT Electrosurgical Unit Hand Instruments

Models: TB-0545PC: THUNDERBEAT 5 mm, 45 cm, Pistol Grip
TB-0535PC: THUNDERBEAT T 5 mm, 35 cm, Pistol Grip
TB-0545IC: THUNDERBEAT 5 mm, 45 cm, Inline Grip
TB-0535IC: THUNDERBEAT 5 mm, 35 cm, Inline Grip
TB-0520IC: THUNDERBEAT 5 mm, 20 cm, Inline Grip
TB-0510IC: THUNDERBEAT 5 mm, 10 cm, Inline Grip
TB-0545FC: THUNDERBEAT T 5 mm, 45 cm, Front Actuated Grip
TB-0535FC: THUNDERBEAT 5 mm, 35 cm, Front Actuated Grip

Lot Numbers: All lot numbers

Dear HealthCare Provider:

Olympus Corporation of the Americas ("OCA") has recently received complaints of damage to the THUNDERBEAT Hand Instruments, models specified above, during surgical procedures. These complaints involve the following or a combination of the following descriptions- cracking, breaking, or deformation of the components of the THUNDERBEAT probe tip or jaw, or the detaching of a fragment from the THUNDERBEAT T probe tip or jaw during or after the surgical procedure. Probe damage detected during surgery will trigger audible and visual generator alarms.

THUNDERBEAT is an electrosurgical unit for use in general (open) and laparoscopic (including single-site surgery) and endoscopic surgery to cut (dissect) or coagulate soft tissue or to ligate (seal and cut) vessels, including urology and gynaecology applications.

Based on its complaint investigations, OCA is providing additional user instructions on procedural techniques to prevent damage to the THUNDERBEAT T hand instruments. Enclosed with this letter please find additional user instruction on Procedural Tips and Techniques for use of THUNDERBEAT. Please make the attached Procedural Tips and Techniques instructions available to all users of the THUNDERBEAT hand instruments. Please also maintain a copy with the Instruction Manual(s) for the device.

****ENDS****

This additional user instruction is also being added to the Instruction Manuals for the THUNDERBEAT T hand instruments. If you would like a copy of the updated Instruction Manual(s), please contact Customer Service at +44 (0) 1702 616333.

Please do not hesitate to contact me regarding any questions you may have on this matter. I can be contacted directly at +44 (0) 1702 616333 or by e-mail at tim.allard@olympus.co.uk

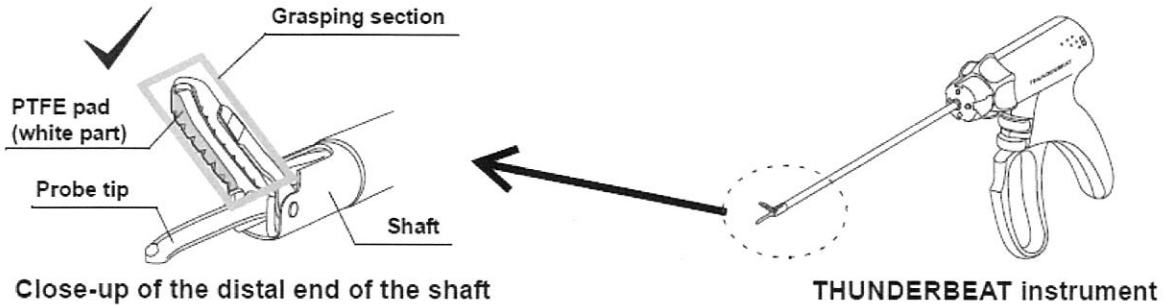
Regards

TIM ALLARD
Regulatory Affairs Manager

NOTE: This quick reference guide is only a summary of the tips and techniques to use THUNDERBEAT. For more detailed operating instructions for the THUNDERBEAT instrument (Item # TB-0545FC, TB-0545PC, TB-0535FC, TB-0535PC, TB-0545IC, TB-0535IC, TB-0520IC, TB-0510IC), please refer to the instruction manual that was included with your THUNDERBEAT instrument when purchased.

PROCEDURAL TIPS AND TECHNIQUES FOR THUNDERBEAT

1 Instrument Nomenclature



2 Potential Damage to the THUNDERBEAT Instrument

Probe tip: Crack and breakage, resulting in falling off into the body cavity

PTFE pad: Deformation, split, protruding, severe wear (Figure 1), and partial separation (Figure 2), resulting in falling off into the body cavity



Figure 1

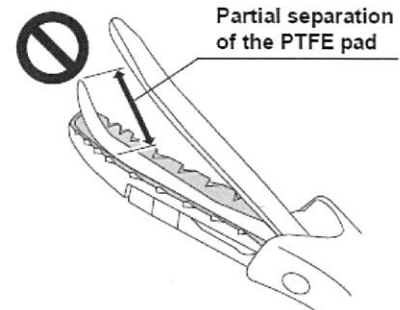


Figure 2

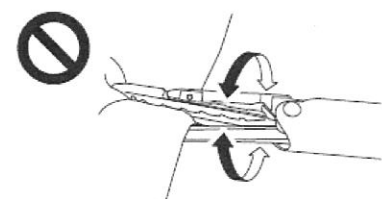
3 Procedural Techniques

Incorrect technique may lead to probe damage error, such as error code "U504" (Probe Damage Error).

If error code "U508" (SEAL & CUT short circuit error) or "U511" (SEAL short circuit error) occurs during use, ensure that no metal object is grasped between the probe tip and the grasping section, and that no body fluid is present around the tip. If the error continues, replace the THUNDERBEAT instrument to avoid damaging the probe tip and/or the PTFE pad.

WARNING

- If error code "U504" (Probe Damage Error) occurs, the THUNDERBEAT instrument must be replaced. Do not turn OFF the USG-400 or disconnect the transducer from it. Do not continue using the damaged probe, as it will cause further development of probe cracks, which may result in probe tip detachment.
- The probe tip and grasping section of the THUNDERBEAT instrument may experience normal wear due to ultrasonic vibrations. Care should be taken to avoid activation of ultrasonic energy (Seal & Cut mode) when tissue is not present in the grasping section. The probe tip and/or the PTFE pad may be damaged. If any visual damage is confirmed on the PTFE pad and/or the probe tip, replace the THUNDERBEAT instrument.
- Do not activate output while grasping hard tissue such as bone or calcified tissue, or hard objects (metal clips, uterine manipulator, etc.). Otherwise, it may cause damage to the probe tip and/or PTFE pad.
- Do not activate output while applying the probe to the tissue with excessive force, grasping thick tissue, or twisting the shaft (Figure 3). Otherwise, it may cause damage to the probe tip and/or PTFE pad.
- Do not use sharp objects (e.g. scalpel) to clean tissue built up on the grasping section or the probe tip. Use a moistened piece of soft gauze to gently clean them instead to prevent any damage to the probe tip.



4 Cutting and Fine Dissection Techniques

WARNING

In Seal & Cut mode, apply light tension to tissue and stop activation immediately after tissue is transected. Do not activate energy without tissue between the probe tip and the grasping section. Otherwise, it may cause damage to the probe tip and/or PTFE pad.

■ Tips

○ TLH colpotomy/amputation techniques: Drilling with small biting method

Narrowly open the grasping section and use the probe tip to drill in laterally at a shallow angle while activating the Seal & Cut mode. Close the grasping section slowly and cut through tissue using the distal half of the grasping section to achieve a slow cut and shallow bites around the cervix. (Figure 4)

WARNING

- 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 (Figure 5). This may result in damage to the probe tip.
- Do not activate the THUNDERBEAT instrument grasping thickly, harder tissue, such as the uterine cervix, with the distal part of the probe tip or the grasping section. This may result in damage to the probe tip.
- Do not use the THUNDERBEAT instrument to position or twist tissue while activating. This may cause damage to the probe tip and/or PTFE pad. Manipulate and isolate the targeted tissue with another instrument, grasp the targeted tissue with the THUNDERBEAT instrument, and then activate.

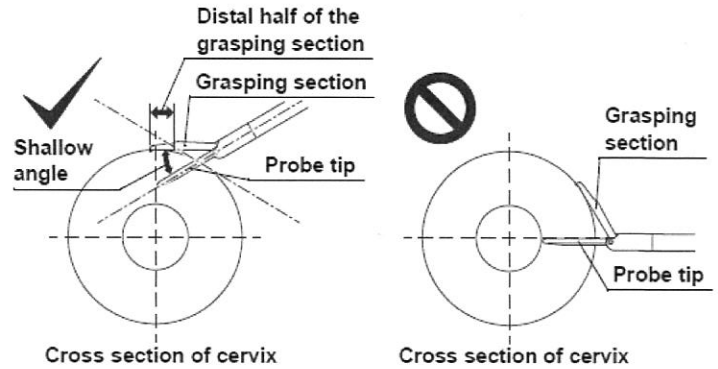


Figure 4

Figure 5

- Avoid contact of uterine manipulators with the THUNDERBEAT instrument, which may cause damage to the probe tip and/or PTFE pad.

5 Vessel Sealing Techniques

Apply and maintain light tissue traction.

Because the probe is one of two bipolar poles, an error code "U514" (SEAL incomplete) may register if the probe tip is surrounded by tissue. To avoid this, rotate the rotation knob so that the probe tip is on top of the tissue.

WARNING

- Squeeze the THUNDERBEAT instrument firmly, closing the grasping section fully on the targeted tissue to apply proper pressure to tissue. Otherwise, incomplete sealing may cause bleeding.
- Do not pull or twist the tissue with a strong force during the procedure. Otherwise, coagulating or sealing may be incomplete.
- Before activating the output, be sure that neither the grasping section nor the probe tip comes into contact with the surrounding tissue. Otherwise, such conditions could potentially reduce the effectiveness of the THUNDERBEAT instrument and could cause unintended tissue damage.
- Confirm that the vessel is in the middle of the grasping section before activating the THUNDERBEAT instrument. If the vessel extends beyond the distal tip of the grasping section, the coagulation may be incomplete.

6 Hemostasis techniques

WARNING

- Confirm that the grasping section and the probe tip are not submerged in fluid (such as puddle of blood or saline) when activated. Otherwise, such conditions could potentially reduce the effectiveness of the THUNDERBEAT instrument and could cause unintended tissue damage.
- In Seal mode, ensure that a bleeding point is grasped between the probe tip and the grasping section. It will not assist in hemostasis to contact the bleeding point with the probe tip and/or the grasping section without grasping.

Manufactured by
MANUFACTURER

OLYMPUS MEDICAL SYSTEMS CORP.

2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan Fax: (042)646-2429 Telephone: (042)642-2111

Distributed by

AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY

OLYMPUS EUROPA SE & CO. KG

(Premises/Goods delivery) Wendenstrasse 14-15, 20097 Hamburg, Germany
(Letters) Postfach 10 49 06, 20034 Hamburg, Germany
Fax: (040)23773-4656 Telephone: (040)23773-0

KEYMED LTD.

KeyMed House, Stock Road, Southend-on-Sea, Essex S52 5QH, United Kingdom
Fax: (01702)465677 Telephone: (01702)616333

OLYMPUS MOSCOW LIMITED LIABILITY COMPANY

117071, Moscow, Malaya Kaluzhskaya 19, bld. 1, fl. 2, Russia
Fax: (095)958-2277 Telephone: (095)958-2245

OLYMPUS AMERICA INC.

3550 Corporate Parkway, P.O. Box 610, Center Valley, PA 18034-0610, U.S.A.
Fax: (484)656-7129 Telephone: (484)656-5000

OLYMPUS LATIN AMERICA, INC.

5301 Blue Lagoon Drive, Suite 290 Miami, FL 33126-2097, U.S.A.
Fax: (305)261-4421 Telephone: (305)266-2332

OLYMPUS (BEIJING) SALES & SERVICE CO., LTD.

A8F, Ping An International Financial Center, No. 1-3, Xinyuan South Road,
Chaoyang District, Beijing, 100027 P.R.C.
Fax: (86)10-5976-1299 Telephone: (86)10-5619-9000

OLYMPUS AUSTRALIA PTY. LTD.

31 Gilby Road, Mount Waverley, VIC., 3149, Australia
Fax: (03)9543-1350 Telephone: (03)9255-5400

OLYMPUS KOREA CO., LTD.

Olympus-Tower, 114-9 Samsong-Dong, Gangnam-Gu, Seoul 135-090 Korea
Fax: (02)6255-3494 Telephone: (02)6255-3210

OLYMPUS SINGAPORE PTE LTD.

491B, River Valley Road #12-01/04, Valley Point Office Tower,
Singapore 248373
Fax: 6834-2438 Telephone: 6834-0010