

October 2015

Safety Advice

Safe use of THUNDERBEAT forceps

Dear Olympus Customer,

Recently, Olympus has received complaints concerning the product THUNDERBEAT.

The aim of this communication is to increase your awareness of the cause of some of these complaints.

To date, no patient injuries have been reported that can be attributed to product failures. The rate of reported product failures is considered to be very low. The complaints generally concern a cracked probe tip, or partial separation or premature wear of the Teflon pad.

As part of Olympus's ongoing commitment to patient safety, we would like enhance your awareness, specifically with regard to the following points:

- Should any irregularity (error messages, abnormal noise, abnormal output, abnormal performance, abnormal appearance, etc.) or malfunction be observed while using THUNDERBEAT, stop use and check the equipment according to the instructions for use in order to avoid any risk of performance deterioration or malfunction.
- 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.

Additionally, please find a quick-reference guide for THUNDERBEAT attached that summarizes selected information important for the proper use of THUNDERBEAT. For complete instructions, please always refer to the instructions for use.

OLYMPUS regrets any inconvenience caused by the implementation of these measures and fully appreciates your prompt cooperation in addressing this situation.

If you have any questions or would like to receive additional training on any aspect of use, care, or maintenance of your THUNDERBEAT system, please contact your local Olympus representative who will be delighted to make the necessary arrangements.

Please fill out, sign, and return the attached reply form to your local vendor/OLYMPUS partner.

Yours sincerely,

