



March 23, 2020

URGENT MEDICAL DEVICE CORRECTION

Attention: Operating Room Manager, Endoscopy Lab Manager, Risk Management Department

**RE: Olympus Pleuravideoscope Models LTF-160 and LTF-240
Recall-0066
All serial numbers**

Dear Health Care Practitioner,

Olympus has become aware of an issue that requires your attention. This letter pertains to the Olympus Pleuravideoscopes models LTF-160 and LTF-240 (“LTF-160” and LTF-240”). The LTF-160 and LTF-240 are indicated for use for endoscopy and endoscopic diagnosis and treatment within the thoracic cavity.

Olympus has initiated this action as a result of assessing the physical compatibility of the Endo-Therapy accessories listed in the LTF-160 and LTF-240 Instruction Manuals. Olympus has determined there is no data demonstrating that the subject Endo-Therapy accessories listed below are compatible for use with the LTF-160 and LTF-240 endoscopes. The risk to patient health is determined to be minor mucosal injury, such as bleeding and scratches, due to use of the Endo-Therapy accessories.

In an effort to mitigate potential risk to patient health, Olympus is requiring that you immediately stop the combination use of the LTF-160 and LTF-240 with the Endo-Therapy accessories in table 1 except for Biopsy forceps FB-55CR-1. Olympus has updated the Operation Manual to remove these Endo-Therapy accessories and the new, revised Operation Manual is included with this letter.

Olympus has not received to date any report of injury with either the Pleuravideoscopes LTF-160 or LTF-240 when used in combination with the Endo-Therapy accessories in Table1.

Table 1

Type of Endo-Therapy accessory	Model Name
Biopsy Forceps	FB-52C-1, FB-34C-1, FB-36C-1, FB-20C-1, FB-35C-1, FB-24K-1, FB-37K-1, FB-11K-1
Spray Catheter	PW-6C-1
Hot Biopsy Forceps	FD-6C-1,FD-7C-1
Injection Needle	NM-4L-1, NM-8L-1, NM-1D
Electrosurgical Knife	KD-31C-1
Electrosurgical Snare	SD-18C-1, SD-7C-1
Coagulation Electrode	CD-6C-1

✖As stated above the accessories in the table should not be used with the pleuravideoscopes LTF-160 and LTF-240. They can be used with other Olympus endoscopes if the IFU of the device indicates the Endo-Therapy accessory can be used with such other endoscopes (GIF,CF,BF and others).

Please report to Olympus any adverse events associated with the use of this device and the accessories that you are aware of or that you become aware of.

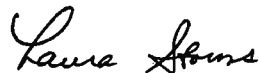
Actions to be taken by the user:

Our records indicate that your facility has purchased one or more of the above-referenced endoscopes. OLYMPUS requires that you take the following actions:

- a) Inspect your inventory of operation manuals for the referenced Olympus models and discard the existing ones.
- b) Exchange them with the updated, enclosed Operation Manuals having an updated system chart indicating compatible endoscope accessories.
- c) Notify related personnel at your institution that they should stop the combination use of the LTF-160 and LTF-240 and the subject Endo-Therapy accessories.
- d) Access the Olympus recall portal to indicate that you have received this notification. Go to <https://olympusamerica.com/recall>. Enter the recall number **Recall-0066** and provide your contact information as indicated in the portal.
- e) If you have further distributed this product, identify your customers, forward them this notification including the attachments, and appropriately document your notification process.

Olympus regrets any inconvenience caused and fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact me directly at (484)896-5688 from Monday till Friday 8AM ET to 5PM ET or by e-mail at laura.storms@olympus.com.

Sincerely,



Laura Storms
V.P., Market Quality

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