

URGENT FIELD SAFETY NOTICE

NOTIFICATION OF INCOMPATIBLE ENDO-THERAPY ACCESSORIES FOR OLYMPUS PLEURAVIDEOSCOPIES LTF-160

Attention: Operating Room Manager, Risk Management Department

| | Model Name | Serial number |
|--------------------------|------------|---------------|
| OLYMPUS PLEURAVIDEOSCOPE | LTF-160 | All |

Dear Health Care Practitioner,

Olympus has become aware of an issue that requires your attention. This Field Safety Notice pertains to the Olympus Pleuravideoscopes LTF-160. The Pleuravideoscope LTF-160 is indicated for use for endoscopy and endoscopic diagnosis and treatment within thoracic cavity. Our records indicate that your facility has purchased one or more of affected LTF-160.

We would herewith like to inform you that the combination of the below Endo-therapy accessories with the LTF-160 did not pass the recent compatibility assessment. If these devices are used in combination within the thoracic cavity, the efficacy (such as the amount of the tissue collected/coagulated or the amount of injection) may be lower than the users expect or minor injuries (scratches or minor bleedings) may occur inside the patient's body.

To date Olympus did not receive any report of injury with the LTF-160 Pleuravideoscopes used in combination with the described Endo-therapy accessories.

In an effort to maximize patient safety and mitigate any potential risk to patient health Olympus is notifying users of the incompatibility of the below mentioned Endo-therapy accessories to Pleuravideoscopes LTF-160 and requires you to **immediately stop using the LTF-160 in combination with the below listed Endo-therapy accessories.**


Table 1: Incompatible Endo-therapy accessories to LTF-160

| 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 |
| Injector | NM-4L-1, NM-8L-1, NM-1D |
| Electro Surgical Knife | KD-31C-1 |
| Electro Surgical Snare | SD-18C-1, SD-7C-1 |
| Coagulation electrode | CD-6C-1 |

The above-mentioned Endo-therapy accessories may be used with **other** Olympus endoscopes **if** the Instruction for Use of the device states the compatibility with such other endoscope (GIF, CF, BF and others)

Note: The Biopsy forceps FB-55CR-1 remains compatible to the LTF-160.

Please find below the revised system chart which you can also find in section **Endo-therapy accessories** of the updated LTF-160 Operation Manual (*GE0220 ver.20, page 48*):

| | |
|------------------|---|
| | BIOPSY FORCEPS |
| | Rat tooth with alligator jaws (Swinging type) |
| |  |
| Endoscope | |
| LTF-160 | FB-55CR-1 |

Advice on actions to be taken by the user:

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

- a) Inspect your inventory of operation manuals for the referenced Olympus models and discard the existing operation manuals.
- b) Exchange them with the updated operation manuals having updated system chart indicating compatible endoscope accessories. (Please refer to attachment 1)
- c) Notify related personnel at your institution that they should stop the combination use of the LTF-160 PLEURA VIDEOSCOPE and the subject Endo-therapy accessories (Please see Table 1).
- d) Indicate on the enclosed Reply Form that you have received and understood this Field Safety Notice.
- e) Send the completed Reply Form back to your Olympus representative (xxx) latest by XXXX.
- f) If you have further distributed this product, identify your customers, forward them this Field Safety Notice including the attachments and appropriately document your notification process.

Your national competent authority has been informed of this Field Safety Notice.

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 Olympus directly at (XXX) XXX-XXXX from Monday till Friday or by e-mail at XXX.

Sincerely,



REPLY FORM – QIL 152-009

| URGENT FIELD SAFETY NOTICE NOTIFICATION OF INCOMPTABLE ENDO-THERAPY ACCESSORIES FOR OLYMPUS PLEURAVIDEOSCOPIES LTF-160 | | | | |
|---|--|--|--|--|
| [Name & Address of Hospital/Medical Facility] | | | | |
| [Dept/Attn] | | | | |
| [Date] | | | | |
| Products available in your facility Please insert the LTF-160 serial numbers available in your facility in the below table | | | | |
| Modelname | Serial number available | | | |
| LTF-160 Pleuravideoscopes | | | | |
| | | | | |
| | | | | |
| Additional Operation Manual request Should you require additional copies of these replacement Operation Manuals, please indicate in the table below the total quantity required | | | | |
| Model name | Quantity of replacement manuals required | | | |
| LTF-160 Pleuravideoscopes | | | | |

I herewith acknowledge the receipt of your Field Notice (FSN) as well as the updated Operation Manual. I understand the necessity to stop using the LTF-160 in combination with the referenced Endo-therapy accessories and 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 fax this completed reply form to Olympus at [contact number] latest by XXXX