



Date: December XX, 2019
Olympus reference: QIL 152-007

URGENT FIELD SAFETY NOTICE

RECALL OF SPECIFIC BF-UC190F BRONCHOSCOPES ON WHICH THE CHANNEL TUBE UNIT HAS BEEN REPAIRED RECENTLY BY OLYMPUS

Attention: Operating Room Manager, Risk Management Department and Reprocessing Units

| Model Name | Description | Only the below listed serial numbers are affected by this FSQA |
|------------------|------------------------|--|
| BF-UC190F | BF-UC190F Bronchoscope | 7800096 |
| | | 7800104 |
| | | 7800106 |
| | | 7900125 |
| | | 7900160 |
| | | 7900161 |
| | | 7900192 |
| | | 7900194 |

Dear Health Care Practitioner,

Olympus has become aware of a matter that requires your attention.

This Field Safety Notice pertains to the above-referenced Olympus BF-UC190F bronchoscopes that were recently repaired by Olympus. Our records indicate that your facility owns one or more of these serial numbers. These endoscopes are designed for endoscopic real-time ultrasound imaging, for performing endoscopic ultrasound guided needle aspiration within the airways, tracheobronchial tree, esophagus and surrounding organs.

The purpose of this Field Safety Corrective Action is to correct a potential quality issue associated with the channel tube unit repaired during the previous repair work on these BF-UC190F bronchoscopes. This quality issue may result in the leakage of the channel tube or the bending section. The risk level has been evaluated as within acceptable based upon the severity level of harm and the occurrence rate. A possible leakage can be detected during the inspection of the endoscope prior to use. To date Olympus did not receive any complaints related to this quality issue.

This action is limited exclusively to repairs done by Olympus on bronchoscopes with the serial numbers listed in the above table.

Olympus requires you to immediately discontinue the use of the devices with the serial number(s) listed above. Please contact your Olympus representative to arrange the return of the affected device(s) to your local service facility.

Olympus will repair these devices at no charge. If Olympus determines during this repair that additional repairs are necessary (unrelated to the potential quality issue relating to adhesive that is the subject of



this Field Safety Corrective Action) to ensure that the device meets its specifications, Olympus may perform such additional repairs prior to returning the device to you. In such cases, Olympus will contact you accordingly prior the repair.

Action Steps:

Our records indicate your facility owns one or more affected BF-UC190F bronchoscope(s) that were recently repaired by Olympus. Therefore, Olympus requires you to take the following actions immediately:

1. Inspect your inventory and identify the specific bronchoscopes with the serial numbers listed.
2. Discontinue the use of the specified BF-UC190F inventory immediately.
3. Contact your local Olympus representative to arrange the return of the device(s). Please always refer to "QIL 152-007". You may also check with your local Olympus representative if it is possible to arrange a loaner for the meantime.
4. Indicate on the enclosed Reply Form that you have received and understood this Field Safety Notice.
5. Send the completed Reply Form back to your Olympus representative (xxx) latest by XXXX.
6. If you have further distributed this product, identify your customers, forward them this Field Safety Notice 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 or on-site support, please do not hesitate to contact Olympus directly at (XXX) XXX-XXXX from Monday through Friday or by e-mail at XXX.

Sincerely,



REPLY FORM – QIL 152-007

| OLYMPUS URGENT FIELD SAFETY NOTICE RECALL OF SPECIFIC BF-UC190F BRONCHOSCOPES ON WHICH THE CHANNEL TUBE UNIT HAS BEEN REPAIRED RECENTLY BY OLYMPUS | | |
|--|---------------|-------------------------------------|
| [Name & Address of Hospital/Medical Facility] | | |
| [Dept/Attn] | | |
| [Date] | | |
| Model | Serial Number | Available in your facility (Yes/No) |
| BF-UC190F | 7800096 | |
| | 7800104 | |
| | 7800106 | |
| | 7900125 | |
| | 7900160 | |
| | 7900161 | |
| | 7900192 | |
| | 7900194 | |

I herewith acknowledge the receipt of your Field Safety Notice (FSN).
Further I confirm that I have transferred the content of the attached to all affected departments on which this action has an impact.
I understand the necessity to return the affected inventory to Olympus for repair and will contact my local Olympus representative accordingly immediately.

Name (Signature) _____

Name (Print) _____

Position _____

Please fax this completed reply form to Olympus at [contact number] latest by XXXX