August XX, 2020
Olympus reference: QIL 153-008

URGENT FIELD SAFETY NOTICE

REMOVAL OF BF-Q180 VIDEO BRONCHOSCOPES

Attention: **Endoscopy Department, Risk Management**

Model Name	Serial Number
Olympus BF-Q180 Video Bronchoscope	all

Dear Healthcare Professional:

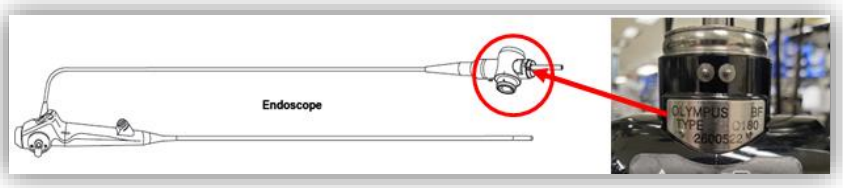
Olympus Medical Systems Corporation ("Olympus") is writing to inform you of a removal action of all EVIS EXERA II BF-Q180 Video Bronchoscopes ("BF-Q180") from the market. The BF-Q180 is intended for use with other equipment for endoscopy and endoscopic surgery within the airways and tracheobronchial tree.

This removal action is being taken after Olympus conducted a postmarket risk assessment of the BF-Q180, including adverse events review, which showed that the BF-Q180 is associated with a higher rate of patient infections than other comparable Olympus bronchoscopes. While this rate of infection is low (less than 0.01%), and patient infection rates depend on a number of factors, out of an abundance of caution and to minimize to the fullest extent possible the risk of infection, Olympus has begun a worldwide transition of the BF-Q180 to newer bronchoscope models.

In the meantime, you may continue to use your BF-Q180 according to the steps described in its Operation Manual and Reprocessing Manual and in alignment with your regional rules related to hygiene monitoring. Any endoscope showing any irregularity should not be used but returned to Olympus.

Action steps to be taken by the end user:
Our records indicate that your facility has purchased one or more BF-Q180 bronchoscopes. Therefore, Olympus requires you to take the following actions:

1. Inspect your inventory and identify any BF-Q180 models. Please check all areas of the hospital to determine if any of these devices remain in inventory. The model and serial number can be found on the device as illustrated in the following picture (Picture 1).



Picture 1: Location of the model name and serial number on the BF-Q180

2. Please fill in the enclosed Reply Form and indicate the serial numbers as well as the total number of BF-Q180 Bronchoscopes in your possession.
3. Send the completed Reply Form back to your Olympus representative (xxx) latest by XXXX regardless of whether you have any affected inventory at your facility.
4. After analysis of your feedback and our production capacity Olympus will contact you end of September 2020 with an exchange proposal.
5. 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 XXXX.
Sincerely,

REPLY FORM – QIL 153-008

OLYMPUS URGENT FIELD SAFETY NOTICE **REMOVAL OF BF-Q180 VIDEO BRONCHOSCOPES**		
[Name & Address of Hospital/Medical Facility]		
[Dept/Attn]		
[**Date]**		
Model name	**Serial numbers still available on stock**	**Total Quantities still available on stock** (If no stock is available please insert 0)
Olympus BF-Q180 Video Bronchoscope		

I herewith acknowledge the receipt of your Field Safety Notice (FSN).
Further I confirm that I have trained the responsible personnel on the actions required in the FSN for the BF-Q180 Video Bronchoscope and transferred the information to all affected departments on which this action may have an impact. I confirm that I have no more affected products on site besides the above mentioned quantities.

Name (Signature) _____

Name (Print) _____

Position _____

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