



August 31, 2020

URGENT: MEDICAL DEVICE REMOVAL ACTION

Attention: **Endoscopy Department, Risk Management**

Product: **Olympus BF-Q180 Video Bronchoscope
All serial numbers**

Dear Healthcare Professional:

Olympus Medical Systems Corporation (“OMSC”) is writing to inform you of a removal action of all EVIS EXERA II BRONCHOVIDEOSCOPE OLYMPUS BF TYPE Q180 (“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 OMSC conducted a retrospective review of past changes to the BF-Q180 applying current FDA guidance for assessing device modifications, including FDA’s 2017 guidance on this topic. Although not every modification to a medical device requires the submission of a new 510(k) to FDA, we now believe, for some of these past changes where we did not submit a 510(k), a better approach would have been to submit a 510(k). However, since this product is now being recalled we do not plan to submit a new 510(k).

As part of this retrospective review, OMSC 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 OMSC bronchoscopes. While this rate of infection is low (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, OMSC has begun a worldwide transition of the BF-Q180 to newer, similarly indicated bronchoscope models.

In the meantime, you may continue to use your BF-Q180 provided you prepare and inspect your endoscope before each procedure, as described in its Operations Manual. Any endoscope showing any irregularity should not be used but rather returned to Olympus for service.

Action steps to be taken by the end user:

Our records indicate that your facility has purchased one or more BF-Q180 bronchoscopes. **OMSC requests 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.



2. Call your Olympus customer service representative at 1-888-524-7266 option 1 to make arrangements to return your BF-Q180 bronchoscope and discuss replacement options. Olympus will issue a Return Material Authorization for you to return any BF-Q180 at no charge.
3. The timing to return your BF-Q180 and receive a replacement product from Olympus will depend on existing inventory. An Olympus representative will inform you of the approximately timing for your return/replacement.
4. In recognition of the need to continue to serve patients, the BF-Q180 may be continued to be used clinically until suitable alternatives are sufficiently available. Olympus recommends continued adherence to the Instructions for Use related to reprocessing. Customers should note that the BF-Q180 has been validated for High Level Disinfection (HLD), Ethylene Oxide Sterilization and Sterrad NX. Clinical support staff is available to answer questions related to all reprocessing procedures.
5. Olympus will reimburse you \$10,000 for each returned BF-Q180.
6. Access the Olympus recall portal to indicate that you have received this notification. Go to <https://olympusamerica.com/recall>. Enter the recall number Recall-0366 and provide your contact information as indicated in the portal.
7. If you may have further distributed the BF-Q180, please identify your customers, notify them at once of this product recall, and appropriately document your notification process. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

The U.S. Food and Drug Administration is aware of the actions described in this letter.

OMSC requests you to report any patient injuries, including infections or persistent microbial colonization associated with any OMSC endoscope. Call our Technical Assistance Center (TAC) at 1-800-848-9024, option 1 to report complaints.

OMSC regrets any inconvenience this action may have caused and fully appreciates your prompt cooperation. If you have any questions or concerns, please do not hesitate to contact me directly at 484-896-5688 or at laura.storms@olympus.com.

Sincerely,

Laura Storms
V.P., Market Quality