



September XX, 2020
Olympus reference: QIL 153-011

URGENT FIELD SAFETY NOTICE

RE: REPROCESSING REMINDER FOR BF-1T180 AND BF-XT160 VIDEO BRONCHOSCOPES

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

	Model Name	Serial number
EVIS EXERA II BRONCHOVIDEOSCOPE OLYMPUS BF TYPE 1T180	BF-1T180	All
EVIS EXERA BRONCHOVIDEOSCOPE OLYMPUS BF TYPE XT160	BF-XT160	All

Dear Healthcare Professional,

Olympus Medical Systems Corporation ("Olympus") is writing to remind you of important reprocessing instructions for the EVIS EXERA II BRONCHOVIDEOSCOPE OLYMPUS BF TYPE 1T180 and EVIS EXERA BRONCHOVIDEOSCOPE OLYMPUS BF TYPE XT160 ("BF-1T180 and BF-XT160"). The BF-1T180 and BF-XT160 bronchoscopes are used with other supporting equipment for endoscopy and endoscopic surgery within the airways and tracheobronchial tree.

Olympus is reminding customers to follow the *Reprocessing Manuals* for manual cleaning and brushing when reprocessing **BF-1T180** and **BF-XT160** devices. Olympus conducted a postmarket risk assessment, which showed that due to the large channel diameter, these devices are associated with a potential risk of patient infection due to inadvertent retention of biomaterial when manual cleaning and brushing are not performed as instructed. If reprocessed according to the *Reprocessing Manual*, we are not aware of any signals that would suggest these devices pose unacceptable risks to patients or users versus the benefits that you have come to trust and rely upon.

Accordingly, it is important to follow the instructions for use for reprocessing these devices, including these manual cleaning and brushing steps. **Please ensure that all reprocessing personnel are completely knowledgeable and thoroughly trained on the reprocessing instructions in the BF-1T180 and BF-XT160 Reprocessing Manuals.**

If you require additional information about the proper steps to clean and reprocess the BF-1T180 and BF-XT160, there are the following ways to obtain this information:

- You can contact your local Olympus organization at XXXXX who can assist in answering questions on BF-1T180 and BF-XT160 cleaning and reprocessing and obtaining additional copies of the *Reprocessing Manuals* and supplemental educational materials.
- The most current language version of the BF-1T180 and BF-XT160 *Operation and Reprocessing Manuals* can be found on the Olympus webpage www.olympus-europa.com under Medical Systems, select Contact & Support. Select Instruction Manual and search for "BF-180" and again for "BF-160".



Actions to be taken by the user:

Our records indicate that your facility has purchased one or more of the above-referenced BF-1T180 and/or BF-XT160 Bronchoscopes. Therefore, Olympus requires you to take the following actions:

1. Carefully read and follow the *Reprocessing Manual* of the affected devices.
2. Indicate on the enclosed Reply Form that you have received and understood this Field Safety Notice and the importance of following the reprocessing instructions carefully by returning the completed Reply Form back to your Olympus representative (xxx) latest by XXXX.
3. If you have further distributed this product, identify your customers, forward them this Field Safety Notice, appropriately document your notification process and let us know accordingly.

This Field Safety Notice pertains to the above-referenced Olympus endoscope models only.

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 till Friday or by e-mail at XXX.

Sincerely,



REPLY FORM – QIL 153-011

OLYMPUS URGENT FIELD SAFETY NOTICE OLYMPUS BF-1T180 & BF-XT160 REPROCESSING REMINDER
[Name & Address of Hospital/Medical Facility]
[Dept/Attn]
[Date]

I herewith acknowledge the receipt of your Field Safety Notice.

Further I confirm that I have transferred the content of the attached FSN to all affected departments on which this action has an impact. I understand the necessity of following the BF-1T180 & BF-XT160 reprocessing instructions carefully.

Name (Signature) _____

Name (Print) _____

Position _____

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