



Date: XX August 2021

Olympus reference: QIL 154-012

URGENT: URGENT FIELD SAFETY NOTICE

ISSUES WITH THE ADHESIVE OF SOME OLYMPUS BF-XT160 BRONCHOVIDEOSCOPE INSERTION TUBES

Attention: Endoscopy Department, Cleaning/Disinfection/Sterilization Department

	Model name	Affected serial numbers		
BF-XT160 Bronchovideoscope	BF-XT160	1200117	2100731	2000693
		1400223	2610953	2400849
		2900652	2600500	2400819
		2400848	2100718	2810999
		2400818	2000666	2610959
		2400840	2810999	2000666
		2100706	1100064	2610958
		2800577	2610955	2810999
		2900614	2610958	2400849
		2610959	2600489	

Dear Healthcare Professional,

Olympus Medical Systems Corporation (“Olympus”) is initiating a corrective action of your Olympus BF-XT160 Bronchovideoscope (“BF-XT160”) with serial number referenced above. The BF-XT160, in conjunction with other Olympus equipment and accessories, is intended to be used for endoscopy and endoscopic surgery within the airways and tracheobronchial tree.

Olympus has initiated this corrective action following discovery that adhesive was not added during a manufacturing step for the insertion tube. Olympus has received no reports or complaints associated with this finding, nor has received any reports of injury. Products manufactured and serviced with these nonconforming insertion tubes passed Olympus inspection and acceptance criteria. However, there is a potential for the insertion tube to develop a leak, which may pose an infection control risk. Accordingly, Olympus is initiating this action to repair your BF-XT160.



Note: Only serial numbers listed in the above table are affected by this FSCA as they contain the referenced insertion tube

Action steps to be taken by the end user:

Our records indicate that your facility has received the referenced bronchoscope from our National Service Center. **Olympus therefore requires you to take the following actions:**

1. Carefully read the content of this Field Safety Notice and ensure that all personnel are completely knowledgeable and thoroughly trained on the content of this FSN.
2. Inspect all BF-XT160 devices in your possession and identify their serial numbers. Please check all areas of the hospital to determine if any of these devices remain in inventory.
3. Please refrain from using the Affected BF-XT160 until completion of the repair or receiving of the loaner scope if your facility has alternative bronchoscopes.
* In case of the only available option for patient care is the use of the BF-XT160 series bronchoscopes, you should give careful consideration if the benefits of conducting the procedure using the BF-XT160 scope outweigh the risks discussed in the letter.
4. Please note on the enclosed FSN Reply Form that you have received, understood, and followed this information. Please include all serial number(s) available in your facility.
5. 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.
6. Olympus will repair your BF-XT160 unit free of charge. An Olympus representative will reach out to you as soon as possible to make arrangements for the return of your affected BF-XT160.
7. If you have further distributed this product, identify your customers, forward them this notification, and appropriately document your notification process.

Your National Competent Authority has been informed of this Field Safety Notice.

Olympus regrets any inconvenience from this corrective action and fully appreciates your prompt cooperation in addressing this situation. Please do not hesitate to contact me directly at [phone number] or at [e-mail] for any additional information or support concerning this matter.

Sincerely,



REPLY FORM – QIL 154-012

URGENT FIELD SAFETY NOTICE	
ISSUES WITH THE ADHESIVE OF SOME OLYMPUS BF-XT160 BRONCHOVIDEOSCOPE INSERTION TUBES	
[Name & Address of Hospital/Medical Facility]	
[Dept/Attn]	
[Date]	
Model name	Affected serial numbers available in your facility
Olympus BF-XT160 Bronchovideoscope	

Dear Sirs or Madams,

I herewith confirm the receipt of your Field Safety Notice. I understand the contents of this letter and have inspected our inventory of Olympus BF-XT160 series bronchoscopes and have identified the affected BF-XT160.

Name (Signature) _____

Name (Print) _____

Position _____

Please scan / email your completed paper form response to XXXX latest by XXXX.