July XX, 2020
Olympus reference: QIL 153-003

URGENT FIELD SAFETY NOTICE

RECALL OF K-401 & K-402 SINGLE USE GUIDE SHEATH KITS FROM THE FIELD

Attention: Operating Room Manager and Risk Management Department

Model Name	Description	LOT No	Remarks
K-401, K-402	Single Use Guide Sheath Kit	**all**	SG-400C guide sheath is included in K-401 and K-402 kits

Dear Health Care Practitioner:

Olympus has become aware of a matter that requires your attention. This letter pertains to the above-referenced Olympus K-401 and K-402 Single Use Guide Sheath Kits ("K-401 & K-402"). The K-401 and K-402 have been designed to be used with Olympus bronchoscopes, EndoTherapy accessories, and/or ultrasonic probes to guide the EndoTherapy accessories and/or the ultrasonic probes to the target area within the respiratory organs and collect tissue, specimens, or cells endoscopically.

Olympus received user complaints indicating that in some instances the SG-400C guide sheath cannot be passed through the bronchoscope instrument channel. This occurred most frequently in combination with the BF-H290 and BF-Q290, however there is a potential that the same issue occurs with other endoscopes having a 2.0 mm working channel (e.g. BF-H190 and BF-Q190).
There has been no adverse event reported to Olympus and there is no safety concern since the SG-400C guide sheath can be safely withdrawn from the endoscope when this event occurs.

After a root cause analysis, Olympus confirmed that due to variation of the outer diameter of the SG-400C guide sheath there is not enough distance between the SG-400C guide sheath's outer diameter and the endoscope instrument channel resulting in occurrences where the SG-400C guide sheath cannot pass through the instrument channel.
To avoid any inconvenience, Olympus decided to recall the subjected kits from the field. If you are also using the K-403 and K-404 kits in your facility, you can continue to use these products as the guide sheath SG-401C that is part of K-403 and K-404 kits is not affected.

Advice on actions to be taken by the user:

Our records indicate that your facility has purchased one or more of the above-referenced K-401 and/or K-402 Single Use Guide Sheath Kits. Therefore, Olympus requires you to take the following actions:

a. Please immediately inspect your inventory for the affected Guide Sheath Kits and identify any of the specified products.
b. Return your K-401 and/or K-402 inventory of the to your local Olympus organization at XXXXXX to get a credit note in return. Please indicate on the enclosed Reply Form that you have received and understood this Field Safety Notice as well as the quantities per model name you are going to return to Olympus.

Olympus will issue a credit note to your facility for any returned complete kits (including the SG-400C guide sheath).

c. 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.
d. 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 XXX.

Sincerely,

REPLY FORM – QIL 153-003

OLYMPUS URGENT FIELD SAFETY NOTICE **RECALL OF K-401 & K-402 SINGLE USE GUIDE SHEATH KITS FROM THE FIELD**
[Name & Address of Hospital/Medical Facility]
[Dept/Attn]
[**Date]**

Model name	**Quantities still available on stock** (If no stock is available please insert 0)	**Quantities to be returned to Olympus** (If no kits will be returned please insert 0)	
K-401 Single Use Guide Sheath Kit			
K-402 Single Use Guide Sheath Kit			

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 K-401 and K-402 Single Use Guide Sheath Kits 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 which I'll return to Olympus immediately.

Name (Signature) _____

Name (Print) _____

Position _____

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