Date: 20-Jan-2025

Olympus reference: QIL FY25-EMEA-28-FY25-013 Guide Sheath Component

URGENT: FIELD SAFETY NOTICE

RE: Single Use Guide Sheath Kit

Attention: Endoscopy Department, Bronchoscopy Suite, Pulmonology, Risk Management

Material ID	Model/Catalog Number	Product Name	Lot Number(s)	UDI PI
N3041830	K-201	Single Use Guide Sheath Kit K-201 2.0MM Channel Set: Guide Sheath, Biopsy Forceps, Cytology Brush	All	04953170245466
N3041930	K-202	Single Use Guide Sheath Kit K-202 2.0MM Channel Set: Guide Sheath, Biopsy Forceps	All	04953170245480
N3042030	K-203	Single Use Guide Sheath Kit K-203 2.6MM Channel Set: Guide Sheath, Biopsy Forceps, Cytology Brush	All	04953170245503
N3042130	K-204	Single Use Guide Sheath Kit K-204 2.6MM Channel Set: Guide Sheath, Biopsy Forceps	All	04953170245527

Dear Healthcare Professional:

Olympus is writing to inform you of a Field Corrective Action pertaining to the Single Use Guide Sheath Kits, models K-201, K-202, K-203, and K-204. These instruments have been designed to be used with an Olympus endoscope to collect cells or tissue specimens in the respiratory organs.

Reason for Action:

Olympus conducted an investigation into the Single Use Guide Sheath Kits after receiving complaints that the radiopaque tip of the guide sheath component (see Figure 1 below), fell off into the patient. Since July 2021, Olympus has received 32 complaints involving intraoperative disassociation of the guide sheath radiopaque tip in which the tip fell off into the patient. Of these 32 complaints, 26 were reported as serious injuries, and 6 were reported as malfunctions. The preliminary findings from Olympus' investigation have identified that the disassociation of the tip from the guide sheath is likely the result of excessive force applied when inserting instruments into the guide sheath, and/or damage to the distal end of the sheath.

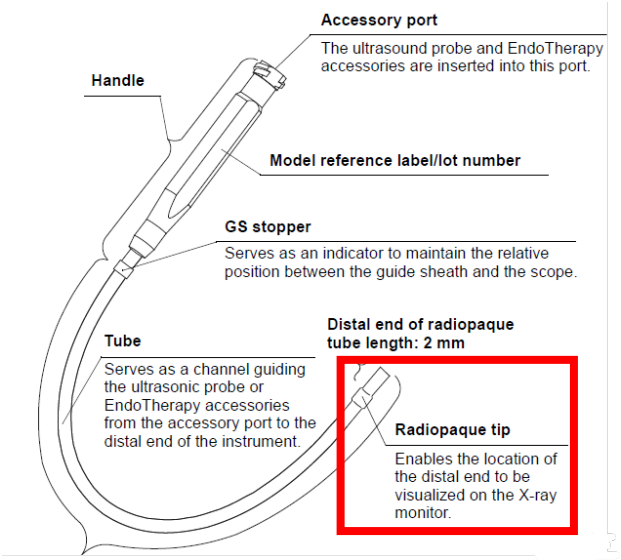

Figure 1: Single Use Guide Sheath (models SG-200C and SG-201C)

Olympus has launched the next generation of the Single Use Guide Sheath Kits, models K-401, K-402, K-403, and K-404, which has a different radiopaque tip design. Therefore, Olympus has discontinued the previous generation models (K-201, K-202, K-203, and K-204) and is removing these models from the market.

You should stop using the K-201, K-202, K-203, and K-204 Single Use Guide Sheath Kits as soon as possible. The next generation Single Use Guide Sheath Kits, models K-401, K-402, K-403, and K-404, should be used by your facility instead.

Risk to Health:

Sudden disassociation of the radiopaque marker from the main body of the guide sheath device while inside the patient during peripheral bronchoscopy can lead to potential patient harm. Consequences of a detached radiopaque marker include the risk of a retained radiopaque marker in the tracheobronchial tree that may require urgent or non-urgent medical intervention for removal and the risk of bleeding, (either immediate or delayed). A prolonged procedure is expected to occur due to the need to either replace the device or proceed with medical intervention. If there is no alternative device replacement available, it could potentially result in the cancellation of the procedure. In any of the above-mentioned events, appropriate medical intervention/management should be based on the clinical circumstance.

Actions Required:

Our records indicate that your facility has received one or more affected units. Olympus requests you to take the following actions:

1. Examine your inventory for Single Use Guide Sheath Kits, models K-201, K-202, K-203, and K-204, and quarantine these devices.
2. **Cease usage of the product with immediate effect.**
3. If you have affected products in your inventory, please contact Olympus at *XXXXX*. Olympus will issue a credit to your facility upon return of your affected product.
4. Olympus requests that you acknowledge receipt of this letter by completing and returning the enclosed Reply Form to your local Olympus representative *[local facility method/contact] by [X date]*.
5. Please forward this notice to other users who may have the affected products if you have further distributed it.

[If applicable:] [competent authority] is aware of the actions described in this letter.
Olympus requests that you report any complaints, including [general issue in letter], to [local facility complaint reporting contact]. [If applicable:] Adverse events experienced with the use of this product may also be reported [local competent authority] by [method].

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact [me directly at XXXX@olympus.com/ Olympus directly at (XXX) XXX-XXXX from Monday through Friday or by e-mail at XXX].

Sincerely,
Name
Olympus title

OLYMPUS

REPLY FORM – QIL FY25-EMEA-28-FY25-013 Guide Sheath Component

Facility Name	
Facility Address	
Contact Name	
Additional Customer Requests (Indicate if you have any additional requests to support this action)	

Insert description of the product names and model numbers of the affected products

Catalog #	Serial / Lot #	Date Shipped	Qty Shipped to your facility	Qty remaining in Stock

I acknowledge receipt of this notification. I confirm that I have further communicated to any affected departments.

Completed By:		
		Click or tap to enter a date.
Name	*Signature*	*Date (YYYY-MM-DD)*

Please send the completed form to *XXX* by date *XXX*.