OLYMPUS

URGENT: MEDICAL DEVICE REMOVAL

Single Use Guide Sheath Kit

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

Date: January 15, 2025

Attention: Endoscopy Department, Bronchoscopy Department, and Risk Management

Dear Healthcare Professional:

Olympus is writing to inform you of a removal action pertaining to the Single Use Guide Sheath Kits, models K-201, K-202, K-203, and K-204, containing Single Use Guide Sheaths, models SG-200C and SG-201C. 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.

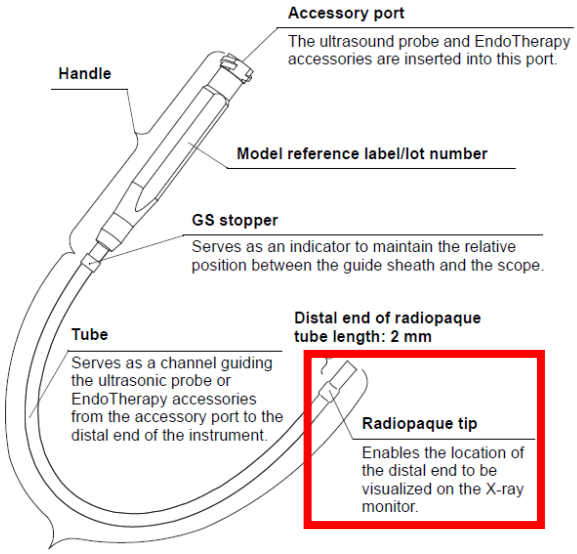

Figure 1: Single Use Guide Sheath (models SG-200C and SG-201C) in Guide Sheath Kits

These products were previously discontinued in 2022 for the US market. Olympus has launched the next generation of the Single Use Guide Sheath Kits, models K-401, and K-402, which has a different radiopaque tip design. Therefore, Olympus is removing the previous generation models (K-201, K-202, K-203, and K-204) from the US 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 and K-402, 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 Customer Service at 1-800-848-9024, option 2, to obtain a Return Material Authorization. Olympus will issue a credit to your facility upon return of your affected product.
4. Olympus requests that you acknowledge receipt of this letter through our Olympus web portal:
    a. Go to https://olympusamerica.com/recall
    b. Enter the recall number "0467"
    c. Complete the form as instructed.
5. Please forward this notice to other users who may have the affected products if you have further distributed it.

Olympus requests you to report any complaints, including device components falling off in patients, to our Technical Assistance Center (TAC) at 1- 800-848-9024, option 1, and the FDA. Adverse events experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact me directly by phone at (647) 999-3203 or by e-mail Cynthia.Ow@Olympus.com.

Sincerely,

Cynthia Ow

Cynthia Ow
Field Corrective Actions Lead, Americas