Date: *XX.XX.XXXX*

Olympus Reference: QIL FY26-EMEA-15-FY26-025-F Resectoscope Resection Sheath

URGENT FIELD SAFETY NOTICE

RE: Resectoscopes Inner/Resection Sheaths
Attention: Urology Department, Risk Management

Affected Products:

Product Name	Model/Catalog Number	Lot Numbers	UDI
RESECTION SHEATH	A22014A	All	04042761020893
RESECTION SHEATH	A22014T	All	04042761020909
INNER SHEATH	A22040A	All	04042761029339
INNER SHEATH	A22040T	All	04042761029360
RESECTION SHEATH	A22041A	All	04042761020961
RESECTION SHEATH	A22041T	All	04042761020978
RESECTION SHEATH	A22042A	All	04042761020985
RESECTION SHEATH	A22042T	All	04042761020992
RESECTION SHEATH	A22043A	All	04042761021005
RESECTION SHEATH	A22043T	All	04042761021012
INNER SHEATH	A2660	All	04042761004176
INNER SHEATH	A2660T	All	04042761004183
RESECTION SHEATH	A2666	All	04042761004244
RESECTION SHEATH	A42011A	All	04042761023658
INNER SHEATH	A4741	All	04042761006514
INNER SHEATH	A2641	All	04042761004060
INNER SHEATH	A2642	All	04042761004084
SHEATH	A37004A	All	04042761023092
INNER SHEATH	WA22017A	All	04042761051514
INNER SHEATH	WA22017T	All	04042761051521

Dear Healthcare Professional/Provider:

Olympus is writing to inform you of a Field Corrective Action relating to the resection/inner sheaths of resectoscopes.

Resectoscopes are intended to be used for endoscope diagnosis and therapeutic procedures. The resectoscopes together with applicable instruments are intended for urologic and/or gynecologic procedures.

Reason for Action:
Olympus has identified complaints related to the ceramic tip of the resection/inner sheath breaking. Over the past three years, there were 146 reports of serious injuries, where the tip fell off during the procedure. In most events, the clinician identified and retrieved the fragment during the procedure. No reports of death have been associated with these events. By nature, ceramics are not pliable and may fracture unexpectedly

under significant mechanical impact. Olympus' investigation revealed that some devices remain in use for prolonged periods and may be subjected to stress over their operational lifetime.

Olympus is highlighting the importance of strictly adhering to the 'Inspection and Testing' and 'Caution' sections in the IFU for the resection/inner sheath, as well as the 'Inspection Before Each Use' section in the Resectoscope System Manual, as illustrated in Figures 1-4 in the appendix. This is crucial to ensure the ceramic tip remains intact, as it will not detach unless it has been damaged prior to use.

Olympus will be updating the instructions for use to instruct users to adhere to the following guidance on preventing or minimizing the likelihood of distal tip damage during the surgical procedure:

- Continue to monitor the device both during and after the surgical procedure for any signs of damage such as cracks, or missing pieces and to assure that there are no fragments left inside the patient. Ensure that an extra resection sheath is available in case of failure so that the surgical procedure can be completed.
- Inspect the device after use prior to sterilization for potential micro cracks, which might lead to a complete crack. Do not use the device if micro cracks are detected.
- Handle the resection sheath with care to avoid damage. Ensure the device does not fall and protect the distal tip from impact.
- To minimize potential long-term stress on the ceramic tip of the resection sheath, the lifetime of the resection sheath is limited to 2 years or 400 uses. Please replace the resection sheath after 2 years or 400 uses.

Risk to Health:

A broken or fractured ceramic tip may cause patient harm, including retention of a foreign body, prolonged operative time, and the need for additional interventions such as imaging or an additional procedure to locate and remove the fragment. Furthermore, exposed sharp edges could result in tissue trauma and bleeding. If a fractured tip is not recognized and a fragment remains in the patient, this could potentially lead to an inflammatory reaction, dysuria, hematuria, pain, urinary retention, and/or a requirement for post-procedure removal.

Actions Required:

Our records indicate that your facility has purchased one or more of the affected products. Therefore, Olympus requires you to take the following actions:

1. Carefully read the content of this letter. Ensure all personnel are fully familiar with the contents of this notification including:
    a. the importance of **adhering to the 'Inspection and Testing' and 'Caution' section of your Instructions for Use for both the resection/inner sheath, as well as the 'Inspection Before Each Use' section in the Resectoscope System Manual as noted above.**
    b. Additional instructions to have an extra resection sheath and inspect during and after the procedure for damage or device fragments.
    c. Supplemental guidance on how to prevent the likelihood of distal tip damage during surgical procedure
2. Add a copy of this letter containing additional instructions with your existing Instruction for Use. The device may continue to be used according to this letter and the instruction for use.

3. Olympus requests that you acknowledge receipt of this letter. Indicate on the Reply Form that you have received and understood this notification by filling out and returning the completed enclosed Reply Form back to your local Olympus representative XXX latest by XXX.

[If applicable:] [competent authority] is aware of the actions described in this letter.
Olympus requests that you report any complaints, 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].

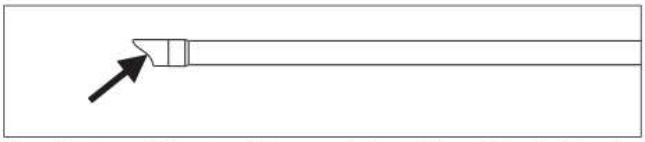
Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact [me directly at XXXX@olympus.com/ Olympus directly at (XXX) XXX-XXXX or by e-mail at XXX].

Sincerely,
Name
Olympus title

Inspection and testing

Inspecting the product
Visually inspect the product. Make sure that it has:
- no corrosion
- no dents
- no scratches

Ceramic insulation at distal end



Visually inspect the sheath's ceramic insulation at the distal end before each use. Do not use the instrument in case of damage (e.g. cracks, fractures).

WARNING
Risk of injury
Impact, fall, shock, or similar stress can result in damage of the ceramic insulation at the sheath's distal end. Damaged instruments can cause injuries of the patient and/or user. Do not use the instrument if damaged.

Damaged product
If the product is damaged or does not function properly, contact an Olympus representative or an authorized service center.

Figure 1. Inspection and Testing – A22014A, A22014T, A22040A, A22040T, A22041A, A22041T, A22042A, A22042T, A22043A, A22043T, A2660, A2660T, A2666, A2666T, A42011A, A4741, WA22017A, WA22017T

Inspection Before Each Use

Before each use, perform the following inspection in addition to that described in the product's product-specific instructions for use.

General inspection
- The product must be free of damage (e.g., dents, cracks, bends).
- The product must be free of dirt.
- The product must be free of remaining cleaning agents or disinfectants.
- Make sure that no parts are missing or loose (e.g., sealing rings, sealing caps).
- Make sure that connecting elements between instruments function properly.
- Inspect working channels for free passage.
- Make sure that all instrument parts/modules of an instrument system are assembled correctly and properly fixed (e.g., electrodes, knives, etc.).

Figure 2. Inspection Before Each Use – A22014A, A22014T, A22040A, A22040T, A22041A, A22041T, A22042A, A22042T, A22043A, A22043T, A2660, A2660T, A2666, A42011A, A4741, WA22017A, WA22017T, A2641,A2642, A37004A

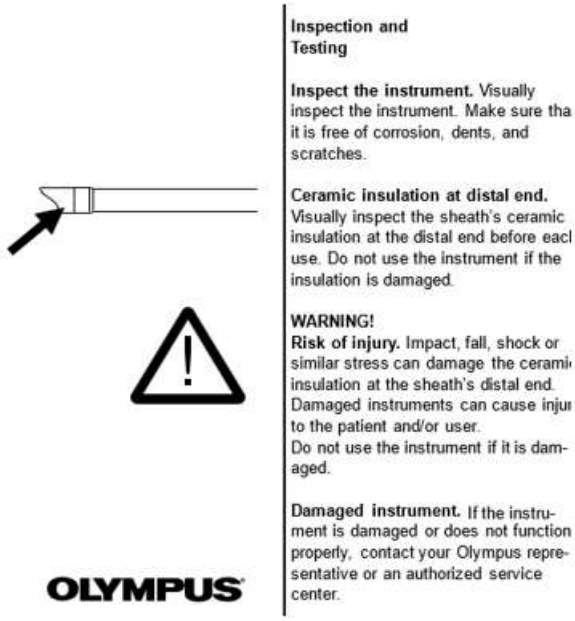


Figure 3. Inspection and Testing – A2641,A2642

CAUTION

Inspect the products

Inspect the products for visible damage. Make sure that the products have:

- no corrosion
- no deformations
- no scratches
- no damaged blade

Do not use damaged products.

Inspection of the sheath

- Before each use, make sure that the ceramic insulation at the distal end is not damaged.
- Do not use a damaged sheath.

Figure 4. Cautions – A37004A

REPLY FORM – QIL FY26-EMEA-15-FY26-025-F Resectoscope Resection Sheath

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

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*.