

Reference: 2025-010M

29 December 2025

## URGENT - FIELD SAFETY NOTICE

To all users of **Olympus** Resectoscopes Inner/Resection Sheath

Product Name	Model/Catalog Number
INNER SHEATH	A22040A
INNER SHEATH	A22040T
RESECTION SHEATH	A22041A
RESECTION SHEATH	A22041T
RESECTION SHEATH	A42011A

### Re: Olympus to Emphasizes Compliance to the IFU and System Manual & To Provide Additional Instructions.

Attention: Urology Department, Risk Management

Dear Healthcare Professional:

Olympus is writing to inform you of a Medical Device 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 require 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 and return the ‘Response Form’ to us.
4. If you have further distributed this product, identify them and forward this notification.

Olympus requests that you report any complaints and adverse events experienced with the use of this product to Olympus.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact us.

### **Contact for enquiries.**

Regulatory Affairs and Quality Assurance Department

Email : [mes-ra.oml@olympus.com](mailto:mes-ra.oml@olympus.com)

Tel : (603) 7650 8990

Fax : (603) 7650 8999

The **Medical Device Authority** has been informed of this notice.

Yours sincerely,

*Hideki Nagai*

Hideki Nagai (Dec 29, 2025 08:40:36 GMT+8)

Hideki Nagai

Managing Director

Olympus (Malaysia) Sdn. Bhd

## URGENT: FIELD SAFETY NOTICE

### RESECTOSCOPES INNER/RESECTION SHEATHS

#### Appendix – Inspection and Testing Instructions from the IFU

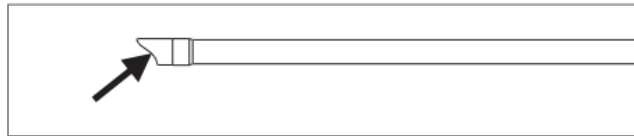
##### Inspection and testing

###### 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 – A22040A, A22040T, A22041A, A22041T, A42011A

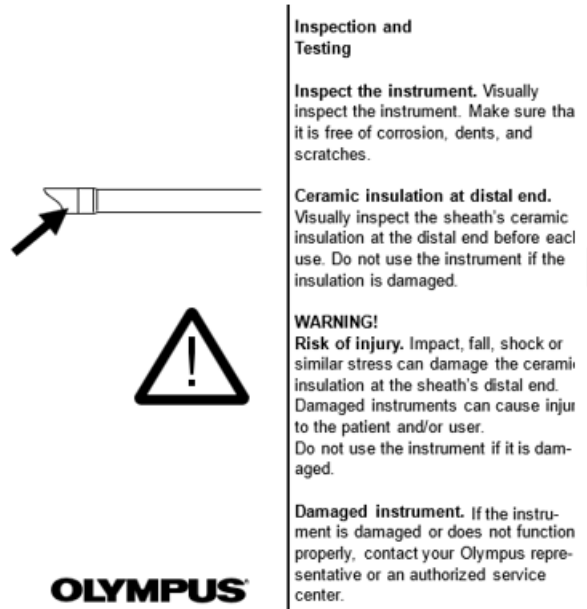
##### Inspection Before Each Use

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 – A22040A, A22040T, A22041A, A22041T, A42011A



## Inspection and Testing


**Inspect the instrument.** Visually inspect the instrument. Make sure that it is free of corrosion, dents, and 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 if the insulation is damaged.

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

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

**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**

## Response Form

Please send the complete and signed Response Form to Regulatory Affairs and Quality Assurance Department at:

To : Olympus (Malaysia) Sdn. Bhd, Regulatory Affairs & Quality Assurance  
Fax/Email : (603) 7650 8999 / [mes-ra.oml@olympus.com](mailto:mes-ra.oml@olympus.com)  
From : \_\_\_\_\_ [Facility Name] Contact no.: \_\_\_\_\_  
Date : \_\_\_\_\_  
Ref : 2025-010M

### **URGENT - FIELD SAFETY NOTICE**

**Re: Olympus to Emphasizes Compliance to the IFU and System Manual & To Provide Additional Instructions.**

I acknowledge receipt of the Field Safety Notice (“FSN”) referenced above. I confirm that I have further communicated to any affected departments.

Check the applicable boxes below:

- I DO NOT have affected product remaining. Product has been condemned or discarded.
- I DO have the affected product, which I will adhere to this FSN letter.

#### **Additional Customer Requests:**

*(Indicate if you have any additional requests to support this action)*

Name: \_\_\_\_\_

Designation: \_\_\_\_\_

.....  
Signature & Company Stamp

.....  
Date






# 2025-010M FSN Customer Letter (1)

Final Audit Report

2025-12-29

Created:	2025-12-29 (Korean Standard Time)
By:	Rohaya Binti Asib (rohaya.asib@olympus.com)
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## "2025-010M FSN Customer Letter (1)" History

-  Document created by Rohaya Binti Asib (rohaya.asib@olympus.com)  
2025-12-29 - 9:33:44 AM GMT+9- IP address: 136.226.234.96
-  Document emailed to Hideki Nagai (hideki.nagai@olympus.com) for signature  
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-  Email viewed by Hideki Nagai (hideki.nagai@olympus.com)  
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-  Document e-signed by Hideki Nagai (hideki.nagai@olympus.com)  
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