

Reference: 2025-X002M

14 October 2025

URGENT: MEDICAL DEVICE REMOVAL

Product: OLYMPUS Single Use Electrosurgical Snare SD-400

Product Name	Model Number	Lot Numbers
SnareMaster Plus Hot/Cold 10mm	SD-400U-10	2YV to 57V*
SnareMaster Plus Hot/Cold 15mm	SD-400U-15	2YV to 54V*

*See Attachment 1 for full list of Lot Numbers

Attention: **Endoscopy Department, Risk Management**

Dear Healthcare Professional:

Olympus is writing to inform you of a Field Corrective Action pertaining to the SD-400U-10 and SD-400U-15 Single Use Electrosurgical Snares (SD-400 Snares). These instruments have been designed to be used with an Olympus endoscope for the removal and/or cauterization of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the GI tract. The SD-400 Snares are sterile, single-use products.

Reason for Action:

During an internal review of the SD-400 Snares sterile packaging process, Olympus discovered holes in a small number of device pouches. Olympus's investigation determined that small holes may occur during packaging of the device pouches into the shelf carton and/or during transportation of the shelf carton. Olympus has not received any complaints related to this issue.

The probability of device contamination resulting from these holes is low. However, any SD-400 Snare package with a hole cannot be considered sterile. Image 1 below shows the area of the sterile pack that is most susceptible to holes as the device may shift within the package during handling.

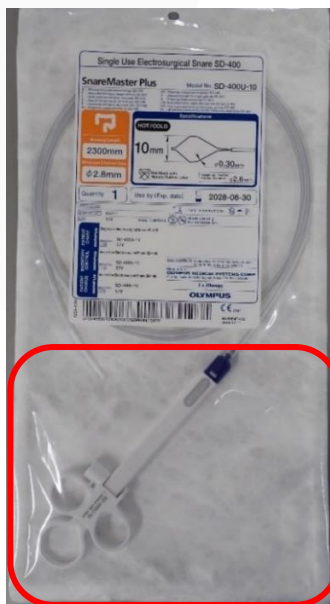


Image 1: SD-400 Snare Sterile Pack

Required Action: Due to the potential sterility breach, you should cease usage of the product immediately.

Risk to Health:

This issue does not impact the functionality of the device; however, if the device packaging has holes and the affected device is used on a patient, there is a potential risk of exposure to a contaminated, non-sterile device, which could lead to infection. Such an infection may require additional medical management, including treatment with oral or intravenous antibiotics. Furthermore, if the issue is identified during package inspection prior to use, it may result in procedural delays while a replacement device is obtained.

Action Required:

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

1. Examine your inventory and quarantine any SD-400 Snares with the lot numbers listed above.
2. **Cease usage of the product immediately.**
3. Olympus will contact you to arrange for return of your device to Olympus, and we will issue a credit to your facility.
4. Olympus requests that you acknowledge receipt of this letter. Indicate on the Response Form that you have received and understood this notification by filling out and returning the completed enclosed Response Form to us.
5. Please forward this notice to other users who may have the affected products if you have further distributed it.

Olympus requests that you report complaints, including holes in device packaging and adverse events experienced with the use of this product to Olympus.

Olympus regrets any inconvenience caused and fully appreciates your prompt cooperation in addressing this matter. If you have any questions or concerns, please do not hesitate to contact us for additional information.

Contact for enquiries

Regulatory Affairs and Quality Assurance Department

Email : 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

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Hideki Nagai

Managing Director

Olympus (Malaysia) Sdn. Bhd

Attachment 1 – Affected Model, Lot

SD-400U-10

2YV	36V	41V	48V	53V
2ZV	37V	42V	49V	54V
31V	38V	43V	4XV	55V
32V	39V	44V	4YV	56V
33V	3XV	45V	4ZV	57V
34V	3YV	46V	51V	
35V	3ZV	47V	52V	

SD-400U-15

2YV	36V	41V	48V	53V
2ZV	37V	42V	49V	54V
31V	38V	43V	4XV	
32V	39V	44V	4YV	
33V	3XV	45V	4ZV	
34V	3YV	46V	51V	
35V	3ZV	47V	52V	

RESPONSE FORM

Medical Device Recall - Acknowledgement and Receipt

Response is required

[Name & Address of Hospital/Medical Facility]
[Dept/Attn]

PRODUCT NAME: OLYMPUS Single Use Electrosurgical Snare SD-400

Product Name	Model Number	Lot Numbers
SnareMaster Plus Hot/Cold 10mm	SD-400U-10	2YV to 57V*
SnareMaster Plus Hot/Cold 15mm	SD-400U-15	2YV to 54V*

Please distribute this information to the appropriate personnel at your facility, including surgeons who may have received the product which is the subject of this recall notice.

I have read and understand the recall instructions provided in the **14 October 2025** letter.

Yes No

Any adverse incidents associated with recalled product?

Yes No

If yes, please explain: _____

Check the applicable boxes below:

I DO NOT have affected device remaining. All have been used or discarded.

I DO have the affected device, which I will return to Olympus.

Lot Number: _____ Quantity to be Returned (UOM): _____

Name: _____

Designation: _____

.....
Signature & Company Stamp

.....
Date

Please send the completed and signed Response Form to Regulatory Affairs and Quality Assurance Department to
[Fax/Email : (603) 7650 8999 / mes-ra.oml@olympus.com]




2025-X002M Recall - Customer Letter

Final Audit Report

2025-10-14

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