Date: 16/10/2025

Olympus reference: QIL FY26-EMEA-12-FY26-033-F SD-400 Sterile Packaging Holes

URGENT FIELD SAFETY NOTICE

RE: Single Use Electrosurgical Snare SD-400
Attention: Endoscopy Department, Risk Management

Material ID	Model Number	Product Name	Lot Numbers	UDI DI
N5998230	SD-400U-10	SnareMaster Plus Hot/Cold 10mm	Please refer to Attachment 1	04953170408243
N5998330	SD-400U-15	SnareMaster Plus Hot/Cold 15mm	Please refer to Attachment 1	04953170408250

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.

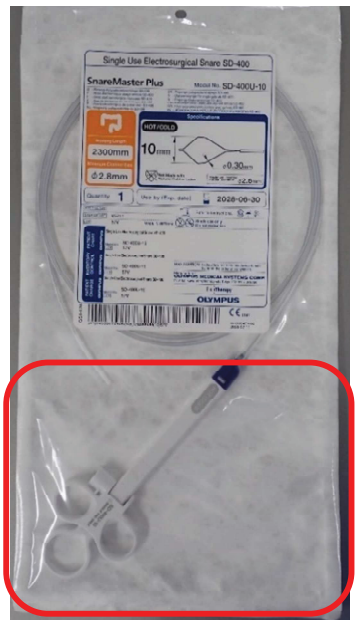

Image 1: SD-400 Snare Sterile Pack

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.

Actions Required:

Our records indicate that your facility has received one or more affected devices. Olympus requires 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. If you have affected products in your inventory, please contact Olympus with regard to return of affected products. Olympus will issue a credit to your facility upon return of your affected product.
4. Olympus requests that you acknowledge receipt of this letter. Indicate on the Reply that you have received and understood this notification by filling out and returning the completed enclosed Reply Form back to your local Olympus representative ra@olympus.co.uk latest by 10/11/2025.
5. Please forward this notice to other users who may have the affected products if you have further distributed it.

Medicines and Healthcare Products Regulatory Agency (MHRA) is aware of the actions described in this letter. Olympus requests that you report any complaints, including holes in device packaging, to concerns@olympus.co.uk. Adverse events experienced with the use of this product may also be reported to the Medicines and Healthcare Products Regulatory Agency (MHRA) online.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact contact charlotte.bell@olympus.com / Olympus directly at 01702 616333 from Monday through Friday or by e-mail at ra@olympus.co.uk.

Sincerely,

Charlotte Bell
Field Safety Corrective Actions & Quality Assurance Projects Manager

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	55V
32V	39V	44V	4YV	56V
33V	3XV	45V	4ZV	57V
34V	3YV	46V	51V	
35V	3ZV	47V	52V	

REPLY FORM: QIL FY26-EMEA-12-FY26-033-F SD-400 Sterile Packaging Holes

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 ra@olympus.co.uk by date 10/11/2025.