

URGENT: MEDICAL DEVICE REMOVAL - UPDATED

Single Use Electrosurgical Snare SD-400

Product Name	Model Number	Lot Numbers	UDI DI	Distribution
SnareMaster Plus Hot/Cold 10mm	SD-400U-10	27V to 57V*	04953170408243	Sept. 2022 to Sept. 2025
SnareMaster Plus Hot/Cold 15mm	SD-400U-15	27V to 55V*	04953170408250**	

*See Attachment 1 for full list of Lot Numbers on 14-Oct-2025

** Corrected UDI on 14-Oct-2025

Date: 14-OCT-2025

Attention: Endoscopy Department, Risk Management

Dear Healthcare Professional:

Olympus is writing to inform you of a Medical Device Removal 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.

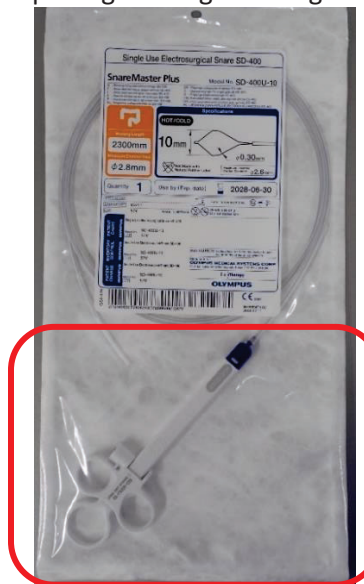


Image 1: SD-400 Snare Sterile Pack

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. 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 recall web portal:
 - a. Go to <https://olympusamerica.com/recall>
 - b. Enter the recall number: "0478"
 - 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 holes in device packaging, 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
Sr. Manager, Field Corrective Action, Americas

URGENT: MEDICAL DEVICE REMOVALSingle Use Electrosurgical Snare SD-400
Attachment 1 – Affected Model and Lot Numbers

SD-400U-10

27V	32V	39V	44V	4YV	56V
28V	33V	3XV	45V	4ZV	57V
29V	34V	3YV	46V	51V	
2XV	35V	3ZV	47V	52V	
2YV	36V	41V	48V	53V	
2ZV	37V	42V	49V	54V	
31V	38V	43V	4XV	55V	

SD-400U-15

27V	32V	39V	44V	4YV
28V	33V	3XV	45V	4ZV
29V	34V	3YV	46V	51V
2XV	35V	3ZV	47V	52V
2YV	36V	41V	48V	53V
2ZV	37V	42V	49V	54V
31V	38V	43V	4XV	55V