

URGENT: MEDICAL DEVICE CORRECTIVE ACTION - UPDATE**SINGLE USE LIGATING DEVICE**

Product Name	Model/Catalog Number	Manufactured Date Range	UDI
SINGLE USE LIGATING DEVICE POLYLOOP	HX-400U-30	22-Sept-2022- 19-March-2026	04953170368615

Date: 20-April -2026

Attention: Endoscopy Department, Risk Management

Dear Healthcare Professional/Provider:

Olympus is writing to inform you of an update to a previously communicated Medical Device Corrective Action relating to the Single Use Ligating Device (HX-400U-30). The Single Use Ligating Device PolyLoop has been designed to be used with an Olympus endoscope to deliver a nylon loop snare intended to prevent or control bleeding following polypectomy of pedunculated polyps.

Olympus has updated the Instructions for Use (IFU) for the Single Use Ligating Device to clarify correct handling and loop-release techniques. The revised IFU includes previously issued guidance as well as supplemental explanations and illustrations intended to clarify the existing guidance. Changes include:

1. Addition of new guidance
 - Releasing the loop while straightening the sheath near the handle
2. Clarification of existing guidance
 - Not holding the loop with the distal end of the tube sheath
 - Releasing the loop while the coil sheath tip is protruding from the tube sheath

The key points to prevent incorrect and incomplete loop detachment including IFU changes have been listed in the attached Attachment 1- "Preventing Incorrect and Incomplete Loop Detachment."

In addition, a Quick Reference Guide showing how to use the single use ligating device is available at the site below:

<https://www.olympusprofed.com/gi/emr/47653/>

Background Reason for Action:

Olympus previously issued a communication dated 3-Nov-2025 to inform users about complaints from customers indicating that the ligation loop was unable to release or detach as expected during use, causing the loop to

become unintentionally anchored in place around patient anatomy. Olympus has identified one hundred and thirteen (113) reports of serious injuries related to this issue. There were no reports of death.

Olympus's investigation into complaints regarding the inability to release the ligation loop found that the failure was caused by the following:

- Inadvertent or intentional movement of the yellow tube joint (cylinder) away from the device handle during use. Intentionally moving the yellow tube joint away from the handle to prematurely tighten the loop during use may cause the inability to release the ligation loop. (See figure 1 below.)
- Forceful advancement of the slider located on the device handle when resistance is encountered may cause an inability to release the loop.

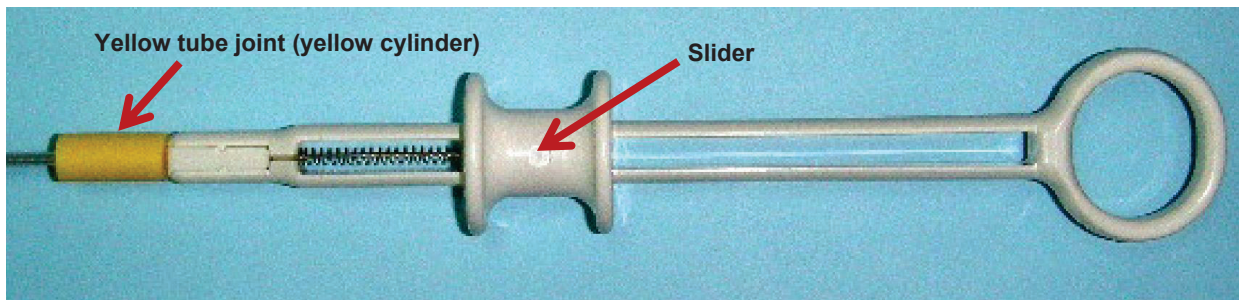


Figure 1

Risk to Health:

As previously communicated, Olympus is reminding users of risk to health:

An unreleased ligation loop stuck within the sheath presents procedural challenges as emergency intervention may be required to remove the device from the patient's anatomy, and the method used for removal significantly influences the severity of these risks. Use of techniques not outlined in the IFU should be avoided unless emergency equipment listed within the IFU is unsuccessful and/or unavailable.

If standard emergency treatment, such as the use of pliers/wire cutters, and a loop cutter is successfully performed as outlined in Section 12 of the IFU, the associated risks are generally limited and may include bleeding and minor procedural delays, which can typically be managed with endoscopic hemostasis clips.

However, if standard removal methods are unsuccessful or not attempted, and alternative techniques are used outside of IFU guidance, the risks are significantly increased, and potential escalation to higher levels of care are possible. The associated risks may include moderate to severe tissue/mucosal injury, bleeding, potentially requiring transfusion, perforation, the need for additional surgical intervention, extensive procedural delays, and hospitalization.

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, including the attachment.

2. Ensure all personnel are completely knowledgeable on the content of this notification. You may continue to use the device and are reminded of the importance of **adhering to the warnings that are present in the instructions for use.**
3. **Replace previous IFU with both the updated IFU and the Preventing Incorrect and Incomplete Loop Detachment from Attachment 1.**
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: "0498"
 - c. Complete the form.
5. If you have further distributed this product, identify your customers, and forward this notification to them.

Olympus requests that you report any complaints 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 by phone at (647) 999-3203 or by e-mail at Cynthia.Ow@Olympus.com.

Sincerely,

Cynthia Ow

Cynthia Ow
Director, Field Corrective Action Execution

Attachment 1 - SINGLE USE LIGATING DEVICE HX-400U-30
Preventing Incorrect and Incomplete Loop Detachment

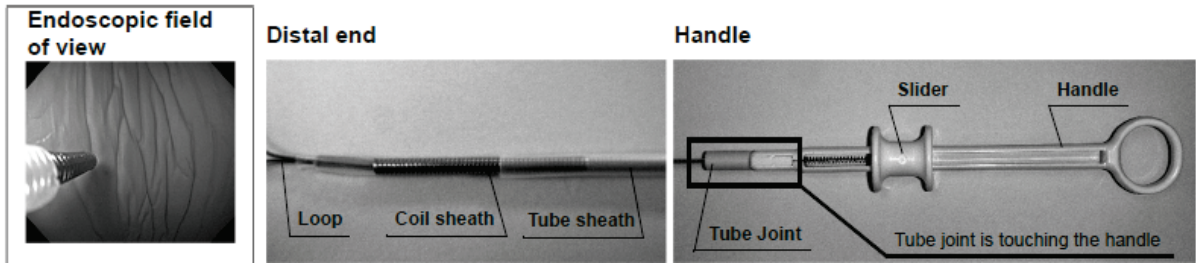
Preventing incorrect and incomplete loop detachment

SINGLE USE LIGATING DEVICE HX-400U-30

This document is a summary. For complete instructions, refer to the full Instructions for Use (IFU), hereafter referred to as "the manual". Before use, thoroughly review the manual and the manuals of all equipment which will be used during the procedure and use the instruments as instructed.

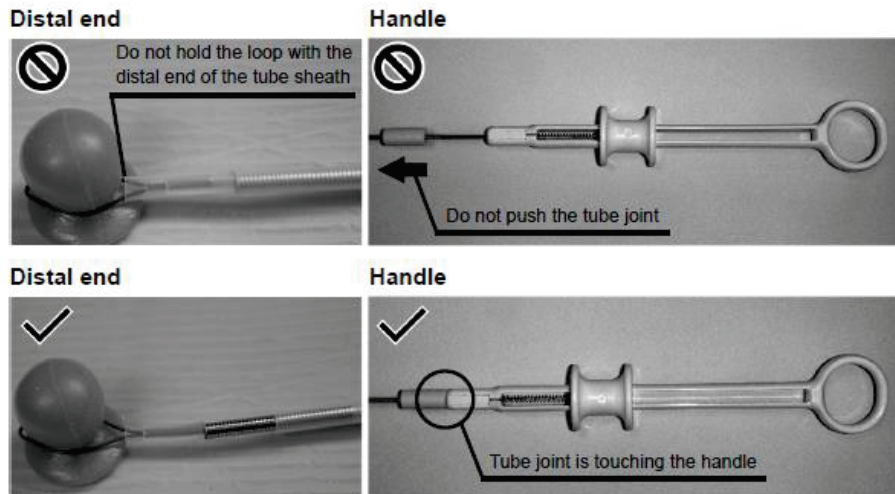
■ **Operation when ligating tissue (refer to page 6 in the manual)**

- Pull the tube joint until it touches the handle to extend the loop from the tube sheath.
- Confirm the endoscopic field of view to see that the coil sheath is extended from the distal end of the tube sheath.



■ **Do not hold the loop with the distal end of the tube sheath while the loop is surrounding the tissue. (refer to page 5 in the manual)**

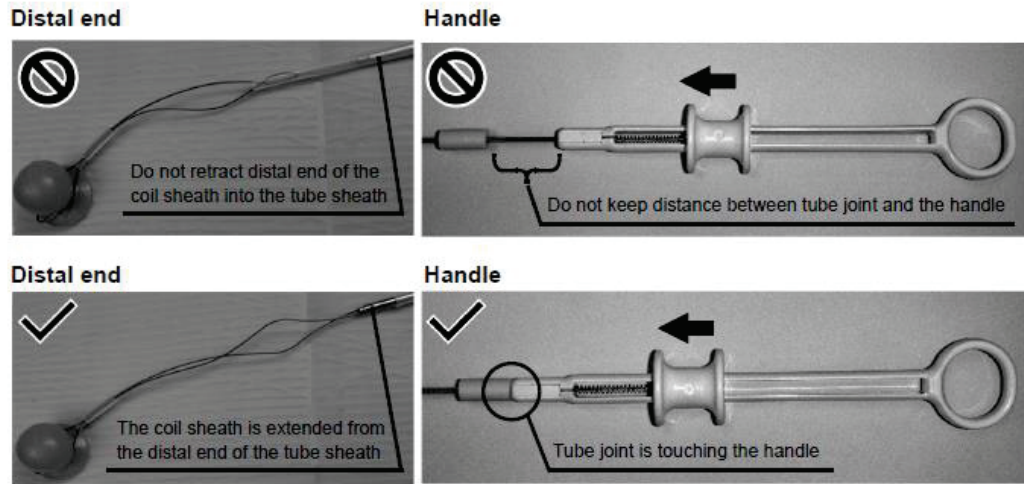
Otherwise, when the tissue is ligated, the loop may be detached from the hook in the tube sheath and tangled with the hook.



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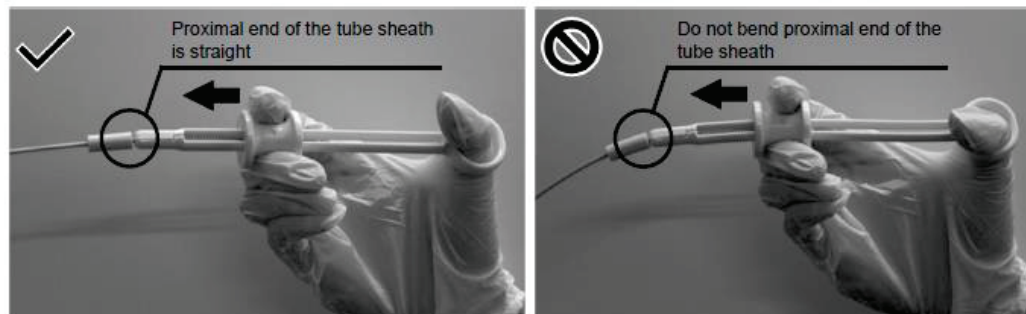
- **Do not remove the loop from the hook while the coil sheath is not extended from the tube sheath. (refer to page 6 in the manual)**

Otherwise, the loop may be tangled with the hook and become impossible to be removed.



- **With the proximal end of the tube sheath and handle kept straight against the biopsy valve of the endoscope, push the slider when detaching the loop. (refer to page 6 in the manual)**

Bending the proximal end of the tube sheath will increase frictional resistance, which may damage the handle when pushing the slider.



■ **Emergency Treatment**

Always have the Olympus loop cutter (FS-5L/Q/U-1), pliers and/or wire cutters ready to cut the coil sheath, tube sheath and operation wire in case the loop cannot be detached from the instrument. In this case, refer to Section 12, "Emergency Treatment" and as shown "Equipment to be used in an emergency" on page 3 in the manual. Use this instrument in an environment equipped to accommodate open surgery and have the hospitalization plan prepared in case any problem occurs that may not be resolved endoscopically.