

URGENT: MEDICAL DEVICE CORRECTIVE ACTION

SINGLE USE LIGATING DEVICE

Product Name	Model/Catalog Number	Manufactured Date Range	UDI
SINGLE USE LIGATING DEVICE POLYLOOP	HX-400U-30	22-Sept-2022- 7-Sept-2025	04953170368615

Date: 3-NOV-2025

Attention: Endoscopy Department, Risk Management

Dear Healthcare Professional/Provider:

Olympus is writing to inform you of a 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.

Reason for Action:

Olympus received 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 preliminary 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.

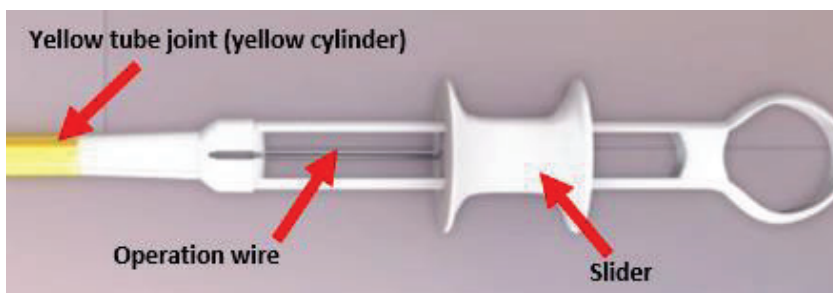


Figure 1

Olympus is continuing to investigate this issue to identify and address any applicable causes, and plans to issue additional communication following the investigation. While Olympus continues its investigation of this issue, **Olympus is reminding users of existing warnings and cautions in the IFU (below). In addition, Olympus is also providing a diagram as supplemental guidance to illustrate the need to maintain a straight position of the proximal end of the tube sheath to prevent increased frictional resistance which may lead to breakage of the operating pipe when the slider is pushed.**

- To detach the loop, ensure the proximal end of the tube sheath and the handle remain straight and aligned with the forceps (biopsy) valve of the endoscope. Then, push the slider as shown in Figure 2. Avoid bending the proximal end, as this increases frictional resistance and may lead to breakage of the operating pipe when the slider is pushed. In this case, refer to Section 12, “Emergency Treatment” and as shown “Equipment meant to be used in an emergency” in the IFU manual.

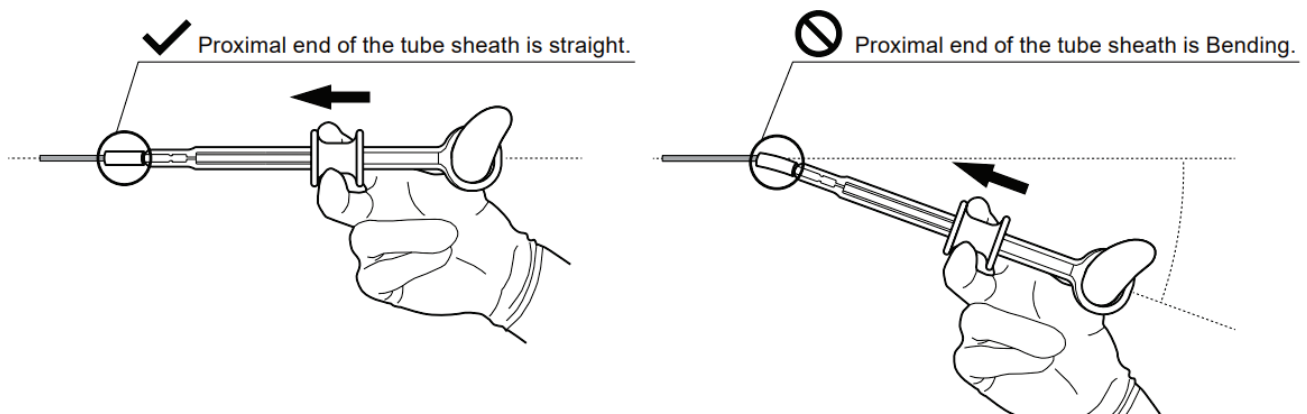


Figure 2.

Users are reminded of the importance of **adhering to the Warnings and Cautions statements that are present in the instructions for use (IFU, ref: GK4574 Rev 16)**. Particular attention should be paid to the following key guidance within Sections 10 and 12 of the IFU (See Appendix 1 of this letter):

NOTE: See Figures 1 and 3 for device image and components described within this document.

- Prepare and inspect the instrument as instructed, should any irregularity be observed, (i.e., deviation or crushed distal end of the coil sheath), do not use the instrument as it may not be possible to detach the loop from the instrument; use a spare instead.
- Never use excessive force to operate the instrument.
- Always have a spare instrument available.
- Always have the Olympus loop cutter (FS-5L/Q/U-1) (FS-410L/U), pliers and/or wire cutters ready to cut the coil sheath, tube sheath and operation wire (See Figure 1 above) in case the loop cannot be detached from the instrument.
- If the loop cannot be detached from the instrument, do not forcibly withdraw it from the endoscope; (doing so could cause patient injury such as punctures, hemorrhages or mucous membrane damage). Follow the emergency procedures described in Section 12 of the IFU. See appendix 1 of this letter.

- Do not remove the loop from the hook while the coil sheath is not extended from the tube sheath. Otherwise, the loop may be tangled with the hook and become impossible to remove. In this case, refer to Section 12, “Emergency Treatment” and “Equipment to be used in an emergency” in the IFU manual.

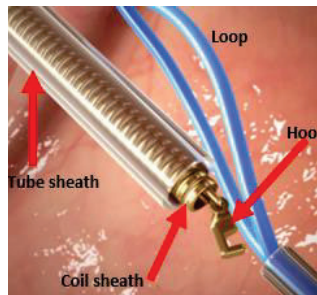


Figure 3.

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 supplemental guidance and reinforced text from the IFU as noted above.
 - a) Always have Olympus loop cutter available when using the PolyLoop device
 - b) When operating the yellow tube joint (yellow cylinder), be careful not to move it away from the handle, prematurely tightening the loop which may cause the inability to release the ligation loop.
 - c) If resistance is encountered, do not continue or force the advancement of the slider located on the device handle.
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. 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: "0476"
 - c) Complete the form.

4. 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 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

10 Preparation, Inspection and Operation

WARNING

- Before use, prepare and inspect the instrument as instructed below. Should the slightest irregularity be suspected, do not use the instrument; use a spare instead. Damage or irregularity may compromise patient or user safety, pose an infection control risk, cause tissue irritation, punctures, hemorrhages or mucous membrane damage and may result in more severe equipment damage.
- Do not strike or crush the coil sheath during operation. Doing so can damage the distal end of the coil sheath, which could make it impossible to detach the loop after ligation. In this case, refer to Section 12, "Emergency Treatment" and as shown "Equipment to be used in an emergency" on page 3 in this manual.

CAUTION

- Never use excessive force to operate the instrument. This could damage the instrument.

10.3 Operation

WARNING

- When removing the hook from the loop, confirm on the endoscopic image that the coil sheath is extended from the tube sheath. Otherwise, the loop may get stuck inside the instrument.

Ligating tissue

WARNING

- Do not remove the loop from the hook while the coil sheath is not extended from the tube sheath. Otherwise, the loop may be tangled with the hook and become impossible to be removed. In this case, refer to Section 12, "Emergency Treatment" and as shown "Equipment to be used in an emergency" on page 3 in this manual.
- Do not hold the loop with the distal end of the tube sheath while the loop is surrounding the tissue. Otherwise, when the tissue is ligated, the loop may be detached from the hook in the tube sheath and tangled with the hook. That may make the loop impossible to be removed. In this case, refer to Section 12, "Emergency Treatment" and as shown "Equipment to be used in an emergency" on page 3 in this manual.

Ligating tissue

1. To ligate the target tissue, angulate the endoscope and/or advance the instrument the required distance.
2. Pull the tube joint until it stops to extend the loop from the tube sheath.

NOTE

When operating the tube joint, be careful not to move the slider.

3. Surround the tissue with the open loop.
4. Pull the slider to ligate the target tissue.
5. Push the slider until it stops to extend the hook from the coil sheath. Detach the loop from the hook.

6 Warnings, Cautions and Notes

WARNING

- Operation of this instrument is based on the assumption that open surgery is possible as an emergency measure if the loop cannot be detached from the instrument or if any other unexpected circumstance takes place. In this case, refer to Section 12, "Emergency Treatment" and as shown "Equipment to be used in an emergency" on page 3 in this 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.

Emergency Treatment

WARNING

Do not try to forcibly withdraw the instrument from the endoscope when the loop cannot be detached from the instrument. Forcibly withdrawing the instrument could cause patient injury such as punctures, hemorrhages or mucous membrane damage.

If the loop cannot be detached from the instrument, follow the procedures described in this section. If there are any deviations or crushed sections on the distal end of the coil sheath, it may not be possible to detach the loop from the instrument.

