OLYMPUS

Date: XX.XX.XXXX
Olympus reference: FY26-006-F-2 Ligature Loop Failures

URGENT FIELD SAFETY NOTICE

RE: SINGLE USE LIGATING DEVICE POLYLOOP
Attention: Endoscopy Department, Risk Management

Material ID	Model Number	Material Description	Lot Numbers	UDI
N5382130	HX-400U-30	SINGLE USE LIGATING DEVICE POLYLOOP	See attachment	04953170368615

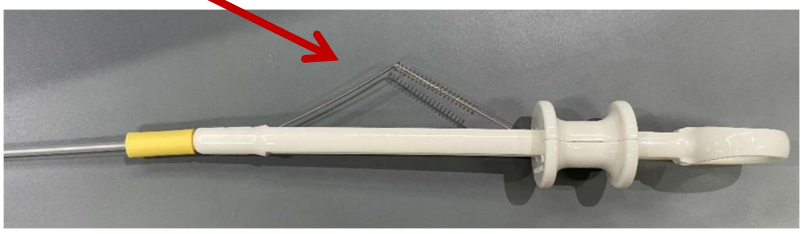
Dear Healthcare Professional/Provider:

Olympus is writing to inform customers who have received the Single Use Ligating Device (HX-400U-30) with lot numbers listed in listed in Attachment 1 about the introduction of a design change. This notification requests the replacement of the previous design of the device.

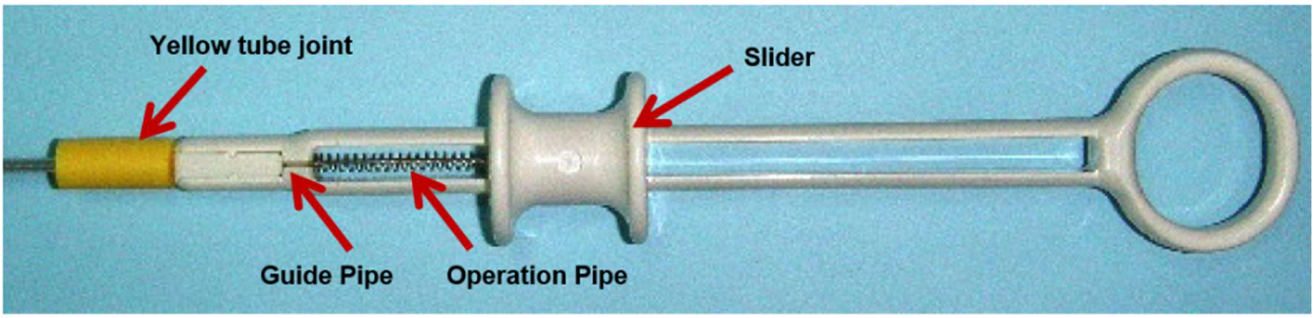
The Single Use Ligating Device PolyLoop has been designed to be used with an Olympus endoscope to deliver a nylon loop snare intended to prevent or control bleeding following polypectomy of pedunculated polyps.

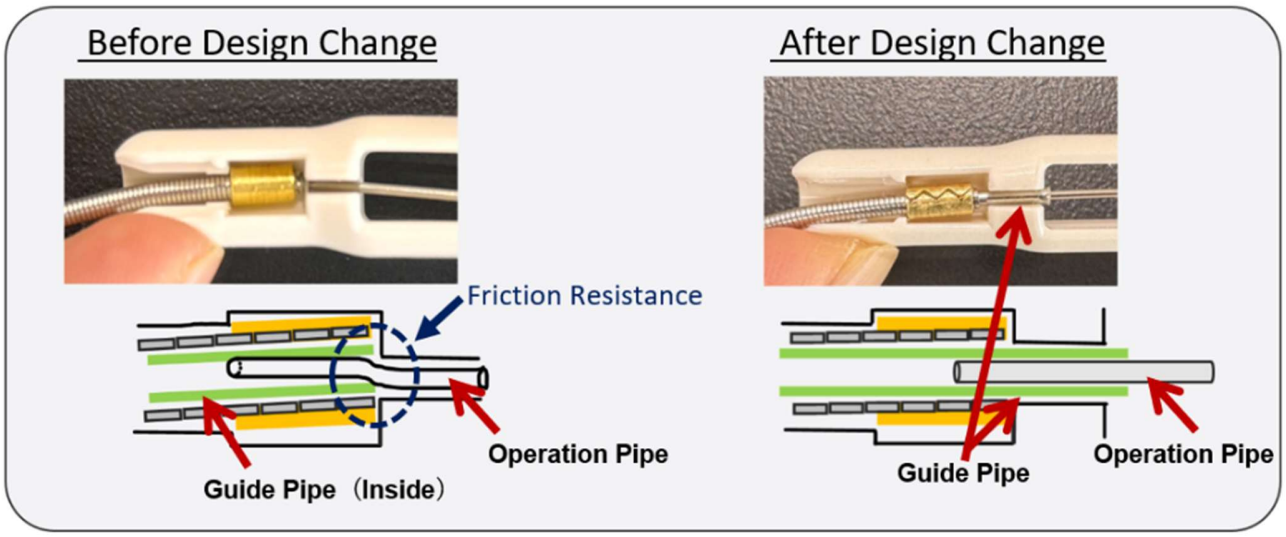
Reason for action:
Olympus is introducing a design change to address complaints that the ligation loop was unable to release or detach as expected during use, with operation pipe breakage being one of the contributing factors to these complaints. (see image below).

Operation Pipe breaking



Olympus revised the method used to secure the guide pipe. As a result, even if the sheath near the handle is not fully straightened, the operation pipe can be prevented from bending as shown in the figure.





Olympus requests that customers replace older versions of the device with the new design and return them to Olympus (refer to Attachment 1). Additionally, Olympus is reminding customers to follow the updated IFU.

Background:
Olympus previously communicated a Field Safety Notice related to additional clarifications in the Instructions for Use (IFU) for proper release of the Single Use Ligating Device (HX-400U-30). Alternatively, customers may have received a Notification of IFU Change with recently purchased products. The action was taken based on 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 previously received one hundred and seventy (170) reports of serious injuries related to this issue and no reported death.

Reminder:
Olympus is reminding customers to follow the updated Instructions for Use to improve correct handling and loop release techniques.

Changes included:

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 2 as a reminder - "Preventing Incorrect and Incomplete Loop Detachment."

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/

Risk to Health:

As communicated in the previous Field Safety Notice, 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. Ensure all personnel are completely knowledgeable on the content of this notification.
2. **All older versions of this product should be returned to Olympus and replaced with the newly designed version.**
   a. **Transition to the newly designed version as soon as possible by placing an order through [Local Customer Service Contact].** You may use the old design of the

device while you await delivery of the new design and follow the updated instructions for use.

3. **Once you have received the new design, stop using the old design and segregate for return to Olympus.**
    a. To return the older version, please contact [Local Customer Service Contact at XXX] to obtain a Return material Authorization.
4. Olympus requests that you acknowledge receipt of this letter. Indicate on the Reply Form that you have received and understand this notification by filling out and returning the completed enclosed Reply Form to your local Olympus representative XXX.
5. If you have further distributed this product, identify your customers, and forward this notification to them.

Olympus requests that you report any complaints, including breakages and detaching components, to [local facility complaint reporting contact]. Adverse events experienced with the use of this product may also be reported [local competent authority] by [method].

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact [me directly at XXXX@olympus.com/ Olympus directly at (XXX) XXX-XXXX from Monday through Friday or by e-mail at XXX].

Sincerely,
Name
Olympus title

Attachment 1 – Medical Device Corrective Action
Affected Lot numbers distributed in [Country/Region]
SINGLE USE LIGATING DEVICE
Model: HX-400U-30

Affected Lot Numbers:			
3XV	4XV	51V	61V
3YV	4YV	52V	62V
32V	4ZV	53V	63V
	41V	54V	64V
	42V	55V	65V
	43V	56V	66V
	44V	57V	
	45V	58V	
	46V	59V	
	47V	5XV	
	48V	5ZV	
	49V		

Attachment 2 - SINGLE USE LIGATING DEVICE HX-400U-30
Preventing Incorrect and Incomplete Loop Detachment

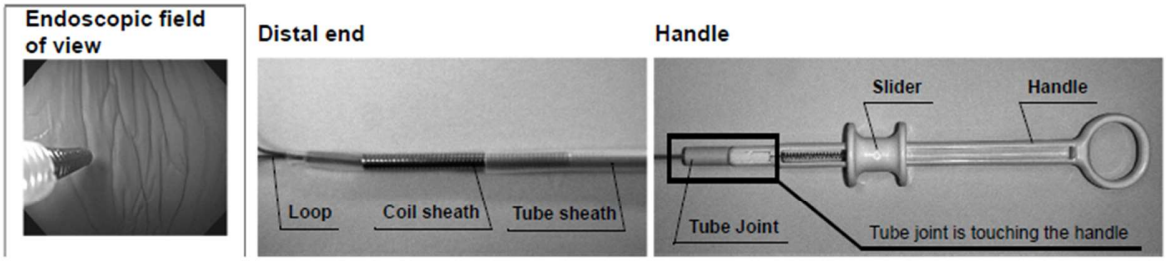
Preventing incorrect and incomplete loop detachment

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.

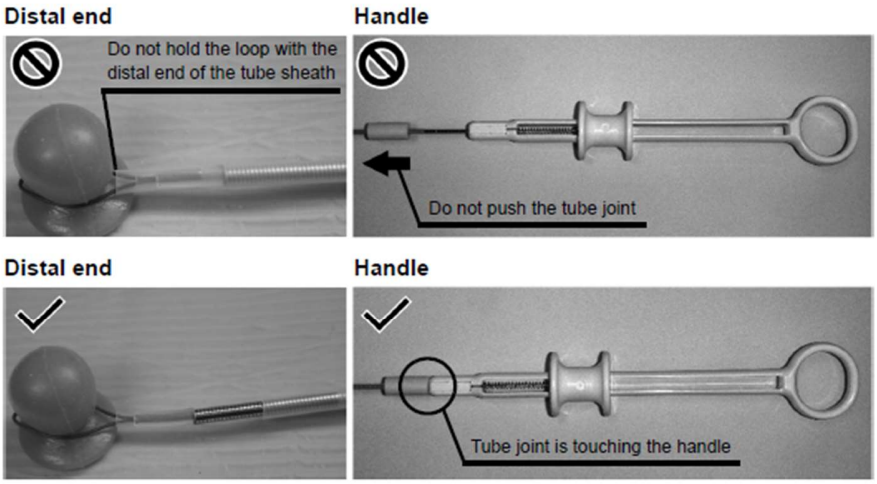
■ *Operation when ligating tissue (refer to page 6 in the manual)*

- 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.

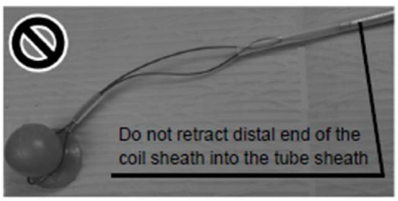


Continued on the next page

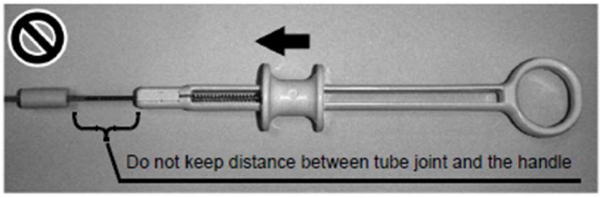
■ *Do not remove the loop from the hook while the coil sheath is not extended from the tube sheath. (refer to page 6 in the manual)*

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

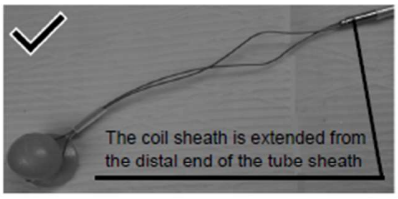
Distal end



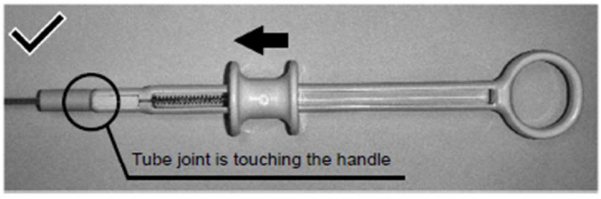
Handle



Distal end

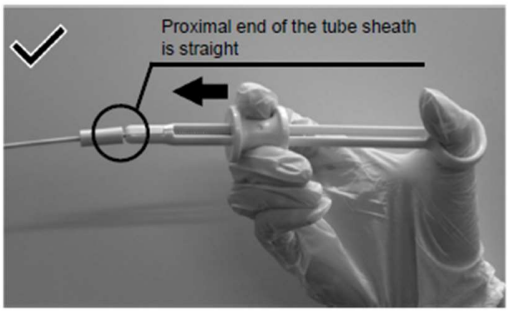


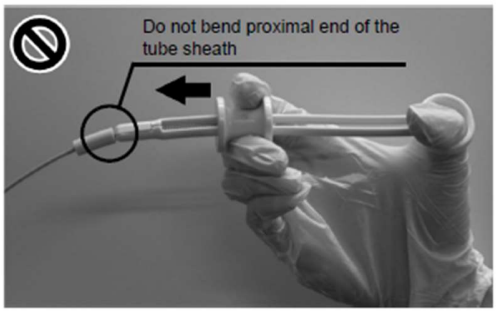
Handle



■ *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.

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Attachment 3: REPLY FORM
FY26-006-F-2 Ligature Loop Failures

Facility Name	
Facility Address	
Contact Name	
Additional Customer Requests (Indicate if you have any additional requests to support this action)	

Insert catalogue number(s), lot number(s) and quantity of the affected products, which remain in your inventory.

Catalogue Number	Lot Number	Quantity

I

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 *XXX* by date *XXX*.