

OPERATING INSTRUCTIONS

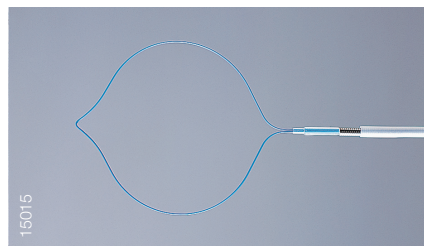
PolyLoop

HX-400U-30

Important

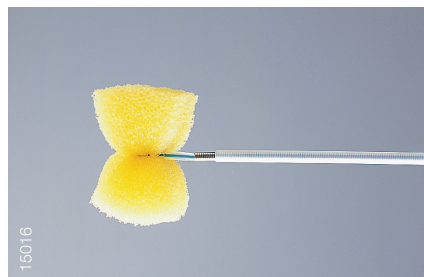
Please refer to the instruction manual provided with the device for complete inspection criteria, warnings, cautions, and instructions prior to use. Preparation before use: Remove the plastic retainer from the loop and extend the tube sheath until the loop is fully covered. Insert the HX-400U-30 through the instrument channel port of the endoscope.

1 | Preparation



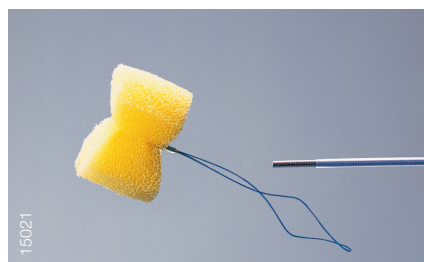
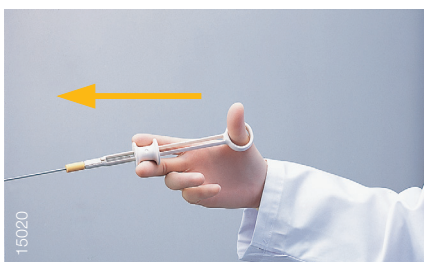
Pull the yellow cylinder proximally until it stops in order for the loop to extend from the tube sheath.

2 | Operation



Position the loop over the target tissue. Then pull the slider proximally to ligate the tissue. Make sure that the coil sheath extends from the tube sheath when removing the hook from the loop after ligating.

3 | Detachment



Push the slider distally until it stops in order for the hook to extend from the coil sheath: Then detach the loop from the hook.

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.

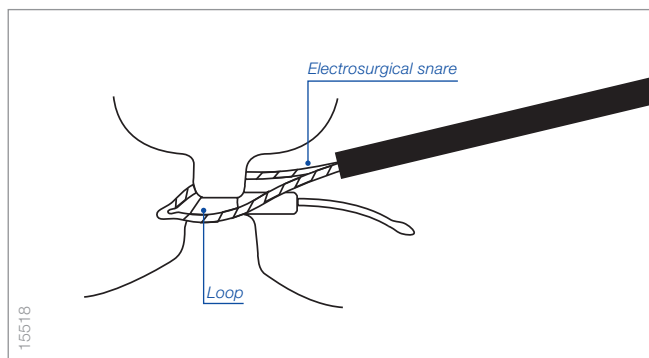
Loop Cutter FS-5L/Q/U-1

Note: If the loop gets stuck in the tube/coil sheath, use Loop Cutter FS-5L/Q/U-1 to cut the loop and to detach it from the device. (Refer to the steps on the back of this sheet for more details.)

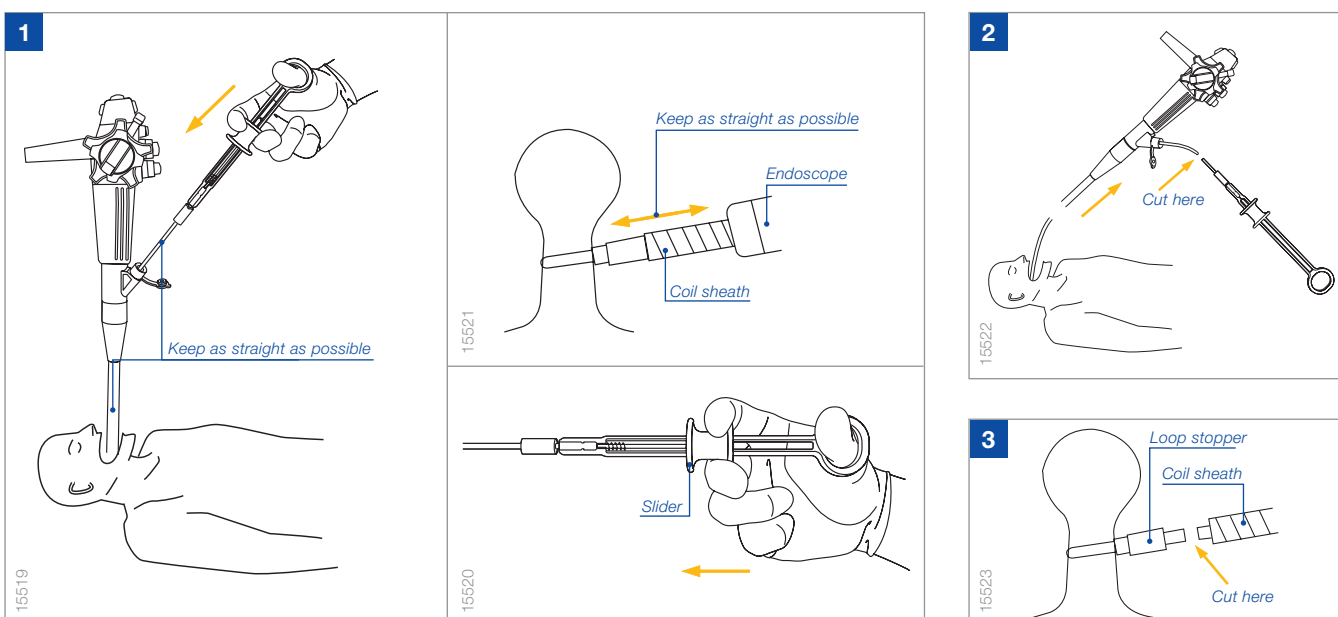


1 | Using an Electrosurgical Snare

- 1 Make sure the tissue has been sufficiently ligated before resecting it. (If the tissue is resected when it is insufficiently ligated, hemorrhaging may occur during or after the operation.)
- 2 When an electrosurgical snare is to be used after ligation, make sure that the loops of the electrosurgical snare and ligating device are not in contact before activating the output. (If the snare and ligating device are in contact when the output is activated, the ligating device's loop may become welded to the snare's loop.)



2 | How to Release the Loop When It is Stuck to the Ligating Device



- 1 Straighten out the portion of the endoscope that extends from the patient, the portion of the ligating device that extends from the endoscope's biopsy valve, and the portion of the coil sheath that extends from the distal end of the endoscope. After pushing the slider proximally until it stops extending the hook from the coil sheath, detach the loop from the hook.
- 2 **If the loop cannot be detached using the procedure in Step 1:**
Cut the tube sheath, coil sheath, and operating wire near the proximal end using pliers or a similar instrument and withdraw the endoscope.
- 3 **If there is a gap between the coil sheath and loop stopper:**
Insert the endoscope along the tube sheath again. Cut the loop where indicated using Loop Cutter FS-5L/Q/U-1. Then withdraw the tube sheath, coil sheath, and operating wire together.

This quick reference guide is a mere summary of some important procedure steps and/or product information. It is not meant to replace the instructions for use. Any user of this product must at all times observe all mandatory information for the product, found, in particular, on the labels and the instructions for use.