Field Safety Notice - Single Use Cold Snare

This Field Safety Notice (FSN) is issued solely for information dissemination and risk communication purposes. In accordance with applicable regulations, this scenario does not require concurrent Field Safety Corrective Actions (FSCA). Based on the risk assessment, the potential risk level is extremely low and fully meets the criteria for issuing an FSN without initiating FSCA. This document has been prepared accordingly.

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I. Information on Affected Device

1.1 Device Name: Single Use Cold Snare
1.2 Trade Name: ScopeSnare Cold
1.3 Reference Numbers (REF): CPS-2410235335, CPS-2410235336, CPS-2415235335, CPS-2415235336
1.4 Intended Clinical Use: Endoscopic removal of diminutive polyps, sessile polyps, pedunculated polyps, and tissue from within the gastrointestinal tract.

II. Product Description and Risk Communication

2.1 Background Information
During endoscopic polypectomy with the Single Use Cold Snare, there is a potential risk of unilateral or complete detachment of the snare loop.

2.2 Probability of Occurrence: Low
The probability of snare loop detachment during endoscopic polypectomy is low. The primary cause may be that large lesions subject the wire to excessive tensile force during the cutting process (e.g., under conditions such as polyps larger than 5 mm). Based on statistical data from 2025 to the present, the occurrence rate for this type of event is 2.23×10^{-5}, which is low.

2.3 Potential Risk to Patients: Low
After snare loop detachment, the exposed sharp wire theoretically presents a potential risk of scratching the digestive tract, causing perforation, or bleeding. To date, in all clinical cases where loop detachment occurred and prompt emergency procedures were performed by the operator, no permanent harm to patients has been reported.

2.4 Recommended Risk Mitigation Measures

To standardize the emergency management of unilateral or complete snare loop detachment during polypectomy, eliminate the risk of tissue laceration, and ensure patient safety, the recommended procedures for the two failure scenarios are outlined below:

2.4.1 Emergency Procedures to Handle Unilateral Snare Loop Detachment

Failure scenario: One side of the wire is still connected inside the connecting tube, while the other side has detached, as shown in Figure 1.

In such scenario, please immediately stop using the snare; do not attempt to continue snaring or resection.

Core principles: Upon the detachment is discovered, immediately stop any snaring or tightening action, keep the instrument fixed in place; do not advance, withdraw, or rotate arbitrarily, to prevent the free sharp wire end from scratching or piercing tissue.

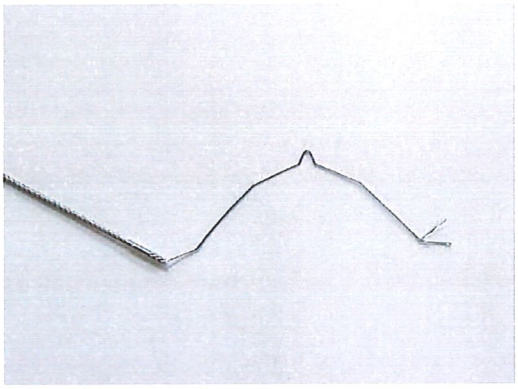

Figure 1: Schematic Diagram of Unilateral Snare Loop Detachment

Recommended procedures:

1) When detachment occurs, slowly and gently retract the handle under the endoscopic view, and try to withdraw the wire completely back into the outer sheath of the snare.
2) If the loop diameter is too large to be retracted into the outer sheath, tighten the handle and then slowly pull back the snare, so that the exposed wire retracts into the endoscope.
3) Replace with a new device to complete the procedure.

2.4.2 Emergency Procedures to Handle Complete Snare Wire Detachment

Failure scenario: The snare loop has completely detached inside the body, as shown in Figure 2.

In such scenario, please follow the endoscopic retrieval method below to avoid injury.

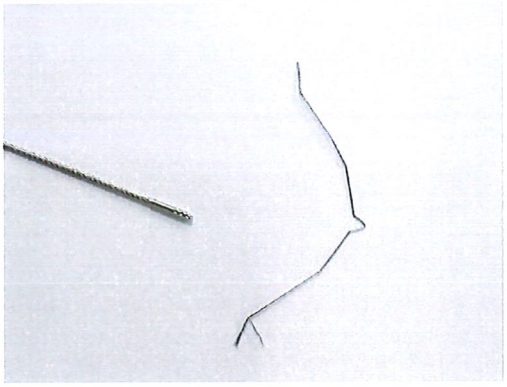

Figure 2: Schematic Diagram of Complete Snare Loop Detachment

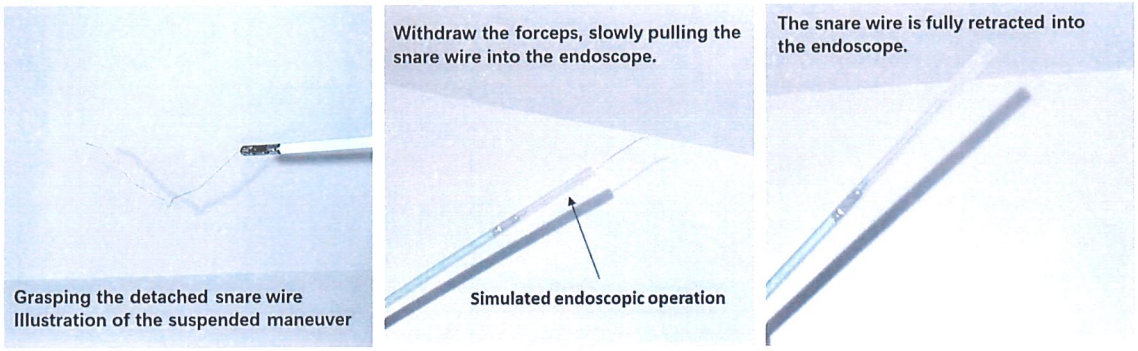

Figure 3: Simulation Illustration
of Endoscopic Retrieval with a Grasping Forcep

Recommended procedures:

1) Position the endoscope tip as close as possible to the wire. Use a grasping forcep to grasp the wire near the endoscope tip, then slowly withdraw the forcep to pull the wire into the endoscopic channel. Then withdraw both the endoscope and the forcep. See Figure 3 for the simulation illustration.
2) If the loop detachment occurs in a large space such as the stomach, first lift the wire away from the mucosa (suspended), then retrieve it using the above method.
3) Replace with a new device to complete the procedure.

2.5 Failure Cause Analysis and Improvement

Regarding the clinical loop detachment issue of Single-Use Cold Snare, the possible cause may be that during the procedure, the polyp being removed was too large, or under other extreme operating conditions, the product was required to withstand greater tensile forces.

According to the product instructions, the intended use of this product is for endoscopic resection of small polyps, sessile polyps, pedunculated polyps, and related tissues in the gastrointestinal tract. When resecting polyps larger than 5 mm, the risk of loop detachment increases accordingly.

To proactively mitigate risks and improve overall product quality and reliability, our company completed product optimization and upgrade in March 2026 (the switching batch number ME260319M303). The specific improvements are as follows:

2.5.1 The dimensional tolerance of the connecting tube was tightened by reducing its inner diameter from 0.6 mm to 0.5 mm, thereby improving the fit tightness between the connecting tube and the snare wire rope and enhancing the tensile strength after crimping. Comparative testing shows that the overall tensile strength between the loop and the pull wire of the optimized product has increased by 15%, achieving a minimum tensile force of 90 N.

2.5.2 The tensile force monitoring standard has been lifted from 50 N to 75 N. This will further help reduce the occurrence probability of loop detachment and better meet clinical application requirements.

Our company will continue to monitor clinical feedback and regularly evaluate product performance to ensure the effectiveness of the implemented improvements.

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