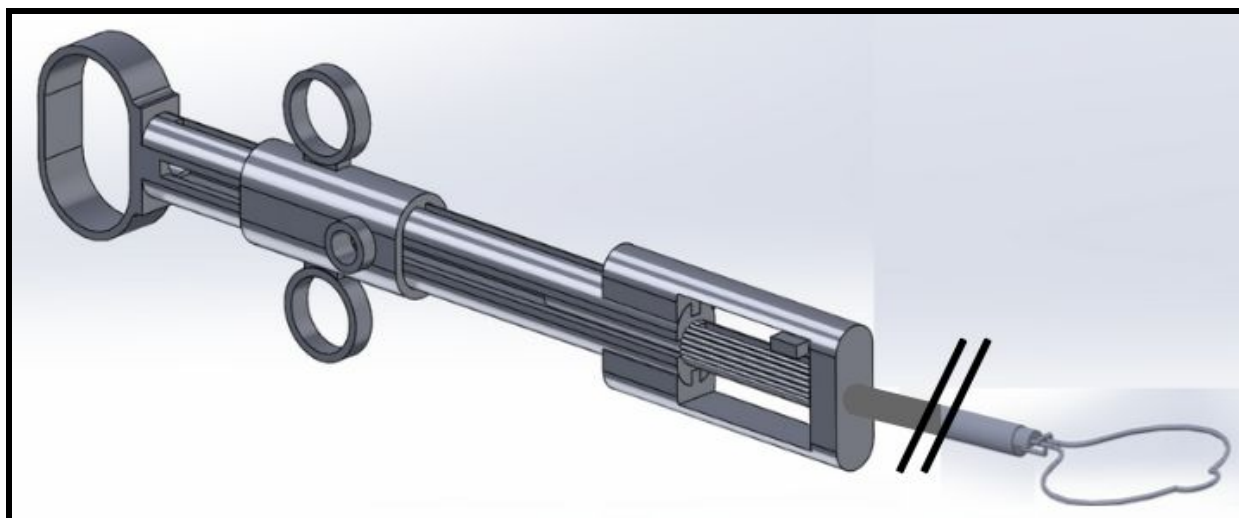


INSTRUCTIONS FOR USE FOR:

TIGER SNARE

**Rotatable & Bendable
Polypectomy Snare**



Manufactured by:
South Flex Medical
301 Rhodes Research Center
Clemson, SC, 29631

Contact Information:
567-203-3717



Consult Instructions For Use



Do Not Use If Package Is
Damaged



Sterilized Using Ethylene
Oxide



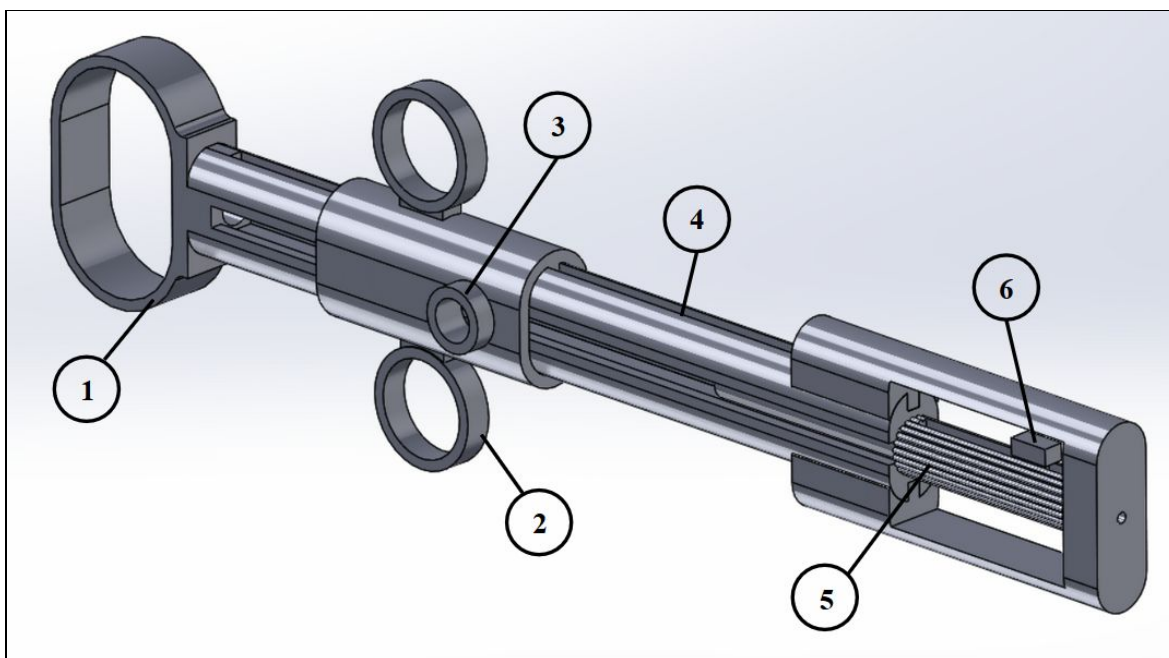
Do Not Re-Use



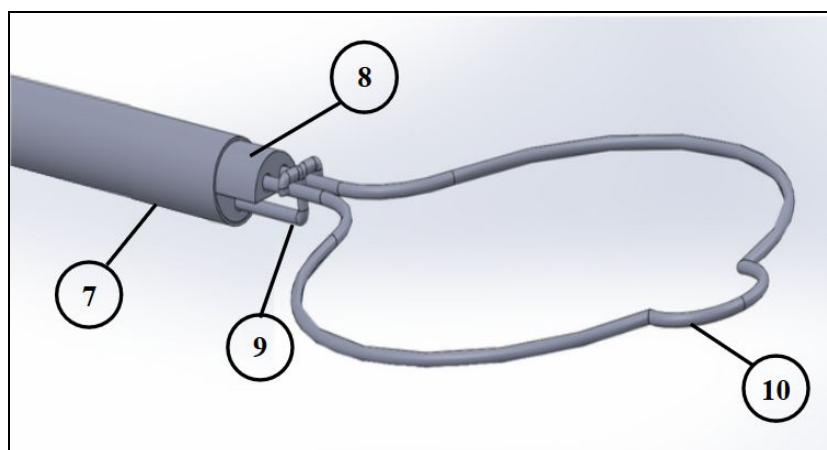
Do Not Resterilize

DEVICE DESCRIPTION

The Tiger Snare is a sterile, single-use device consisting of a three-ring handle component coupled with a tubing system that is threaded with a stainless steel wire to form the snare loop at the distal end. The tubing assembly features a 240 cm working length with an outer sheath diameter of 2.4 mm, and the snare loop expands to a maximum of 20 mm for large polyps. It is intended to be coupled with endoscopes for the removal of polyps and redundant tissues with or without high-frequency current within the gastrointestinal tract.



HANDLE COMPONENT



TUBING SYSTEM

PART			DESCRIPTION
1	Handle Component	Thumb Loop	Loop to hold the thumb to anchor and stabilize the device during sliding
2		Sliding Handle	Two ring sliding handle to alter the diameter of the snare loop
3		Electrocautery Port	Port to connect the device to a high frequency generator via an active cord
4		Handle Base	Housing for the internal sliding, rotating, and bending mechanisms
5		Rotation Control Wheel	Wheel to control snare loop rotation in both the clockwise and counterclockwise directions
6		Bending Control Slide	Slide to axially bend the snare loop down to a 45 degree angle
7	Tubing System	Outer Sheath	Housing to protect the inner sheath
8		Inner Sheath	Compartmentalized tubing to securely house the bending wire and the snare loop wire
9		Bending Wire	Wire secured to the base of the snare loop to control the degree of bending
10		Snare Loop Wire	Wire used to surround and resect the polyps

INTENDED USE

The Tiger Snare is indicated for use endoscopically for the removal and/or cauterization of diminutive polyps, sessile polyps, pedunculated polyps, and tissue from within the gastrointestinal tract.

CONTRAINDICATIONS

The Tiger Snare is contraindicated for use in:

- Patients who have the contraindications for digestive endoscopic examination
- Patients susceptible to hemorrhages

- Patients with deteriorated colon cancer
- Areas in the colon that are likely to hemorrhage
- A polyp with a base diameter greater than 3mm
- A bowel that was insufficiently prepared for polyp removal

WARNINGS



DO NOT use if package is damaged. DO NOT use if the product sterilization barrier or its packaging is compromised.

- Device should only be used under the direct supervision of a trained endoscopic and tissue resection physician.
- It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of this device.
- High-frequency generator should be set to OFF when electrocautery is not in use.
- Ensure the patient is properly grounded before utilizing electrocautery.
- Read instructions for use completely prior to use.
- Contents are sterile unless packaging is opened or damaged.
- For single-use only.
- Discard any open, unused product.

DO NOT USE IF:

1. Package is damaged or open when received.
2. The device has abnormalities.
3. The device is expired.
4. The device has already been used (DO NOT RESTERILIZE).
5. The endoscopic Channel is smaller than 2.8mm.

6. The patient has a pacemaker (consult patients cardiologist and pacemaker manufacturer before proceeding with the procedure).
7. The cauterization connection is not fully seated within the port ensuring full connection the entire procedure.
8. The cauterization machine has power above 30 watts, peak voltage is above 1600 Vp during cutting mode, or above 2300 Vp during cauterization mode.

PRECAUTIONS



U.S. Federal law restricts this device to sale by or on the order of the physician.

- Hazards associated with the reuse of this device include, but are not limited to, patient infection and/or device malfunction.
- Prior to use, inspect the device to ensure it is not damaged. DO NOT use damaged device.
- Excessive Force should NEVER be used when retracting, rotating, or bending the snare loop
- Potential complications associated with polypectomy procedures include, but are not limited to: perforation, hemorrhaging, infection, burning, and hypertension.
- After use, this device may be a potential biohazard and should be handled in accordance with accepted medical practice and applicable local and national requirements.

DIRECTIONS FOR USE - NO ELECTROCAUTERY

1. Remove the Tiger Snare from the packaging. If there are any rips or tears in the packaging prior to opening, DO NOT use the device, and report the device to South Flex Medical.
2. Inspect the device for damages or malformations. If damages are observed, DO NOT use the device, and report the device to South Flex Medical.
3. Maneuver the sliding handle up and down the handle base to ensure that the loop can achieve full extension and retraction. Ensure the snare loop does not have any deformations, frays, or sharp protrusions. DO NOT use if any damage is found.

4. Before entering the endoscope, retract the snare loop into the outer sheath by bringing the sliding handle toward the thumb loop. Ensure that the entire loop is fully retracted into the outer sheath. See **Image 1** below.

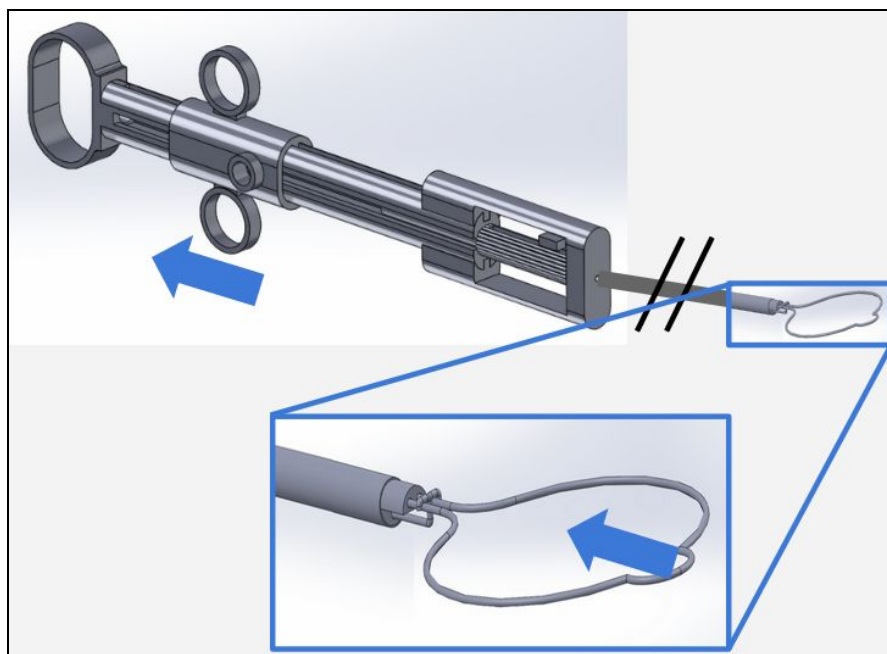


IMAGE 1

5. Once the endoscope has visualized a polyp to be removed, ensure that the snare loop is fully retracted, and insert the outer sheath of the Tiger Snare into the instrument channel of the endoscope. Continue to advance the sheath into the channel until the sheath has exited the port at the distal end of the endoscope.
6. Once the end of the sheath is visualized via the endoscope, maximally extend the snare loop, maneuvering the sliding handle in the opposite direction as **Image 1**.
7. If rotation is desired to better access the polyp, rotate the rotation wheel on the handle component. To turn the snare loop clockwise, rotate the wheel to the right. To turn the snare loop counterclockwise, rotate the wheel to the left. See **Image 2** below.

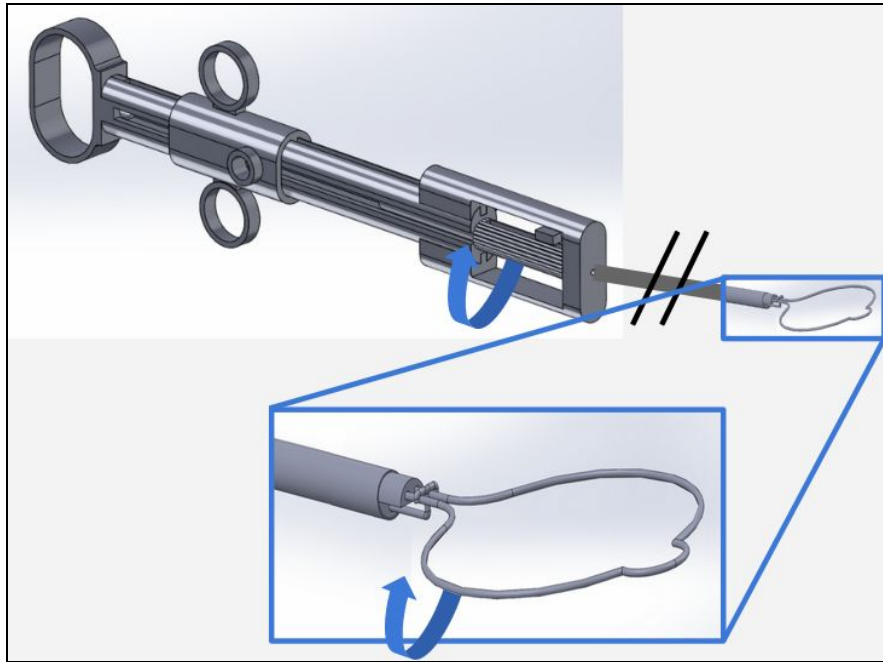


IMAGE 2

8. If bending is desired to better access the polyp, slide the bending control slide towards the thumb loop in order to bend the snare loop down. To return the snare loop to neutral orientation, release the bending control slide to the starting position. See **Image 3** below.

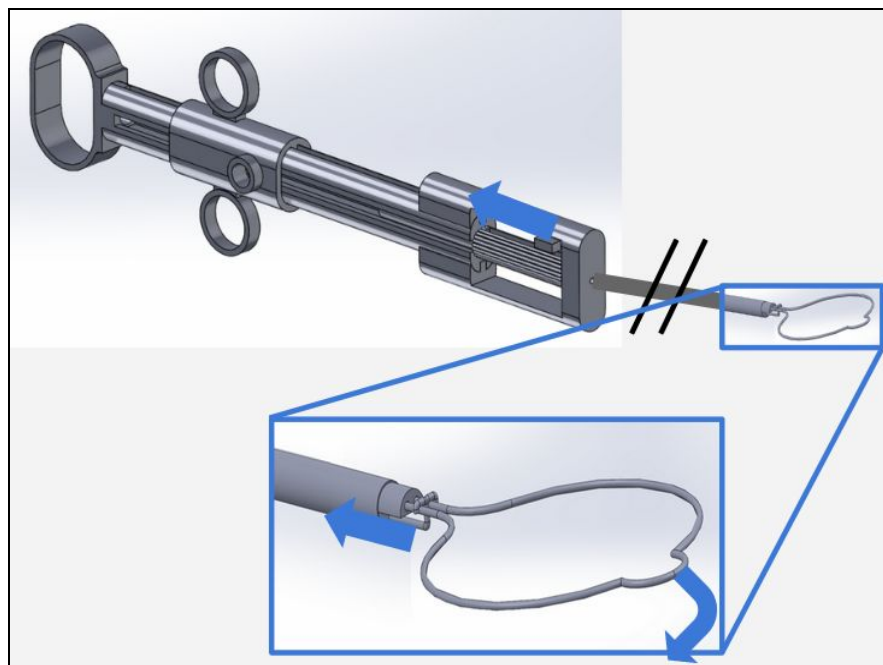


IMAGE 3

9. Once the desired snare loop orientation is achieved, ensure the snare loop is at full extension, and maneuver the loop around the base of the polyp as shown in **Image 4** below.

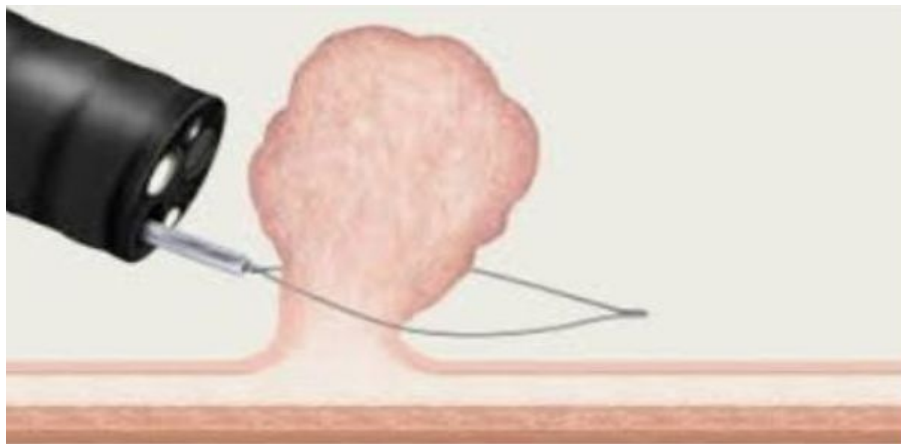


IMAGE 4

10. When the snare loop is secured at the base of the polyp, retract the sliding handle toward the thumb loop as shown in **Image 1** until the polyp is fully resected.
11. After the procedure is complete and the desired polyps have been removed, carefully withdraw the outer sheath from the endoscope.
12. Properly dispose of the Tiger Snare in the hazardous waste bin.

DIRECTIONS FOR USE - ELECTROCAUTERY

1. If electrocautery is desired to remove a particular polyp, complete the non-electrocautery directions 1-3 as shown above.
2. Select the appropriate active cable to connect with the electrocautery port in the handle. Insert the other end of the cable into the appropriate high-frequency generator. Ensure the units are securely connected.
3. Set the high-frequency generator to OFF before inserting the snare into the endoscope, so as to avoid patient injury or equipment damage caused by improper circuit grounding.
4. Ensure the patient is properly grounded before activating electrocautery.
5. Continue to complete non-electrocautery directions 4 - 9 as shown above.
6. As the snare loop is oriented around the base of the polyp, set the high-frequency generator to ON.

7. Engage the electrocautery by pressing the electrosurgical unit's foot pedal. Retract the snare loop as necessary as shown in **Image 1** until the polyp is fully resected.
8. Once resected, release the foot pedal of the electrosurgical unit.
9. Turn the electrosurgical unit to OFF.
10. Repeat electrocautery steps 6 - 9 as needed.
11. Disconnect the electrosurgical unit cord from the electrocautery port of the Tiger Snare.
12. Continue to complete non-electrocautery directions 11 - 12 as shown above.

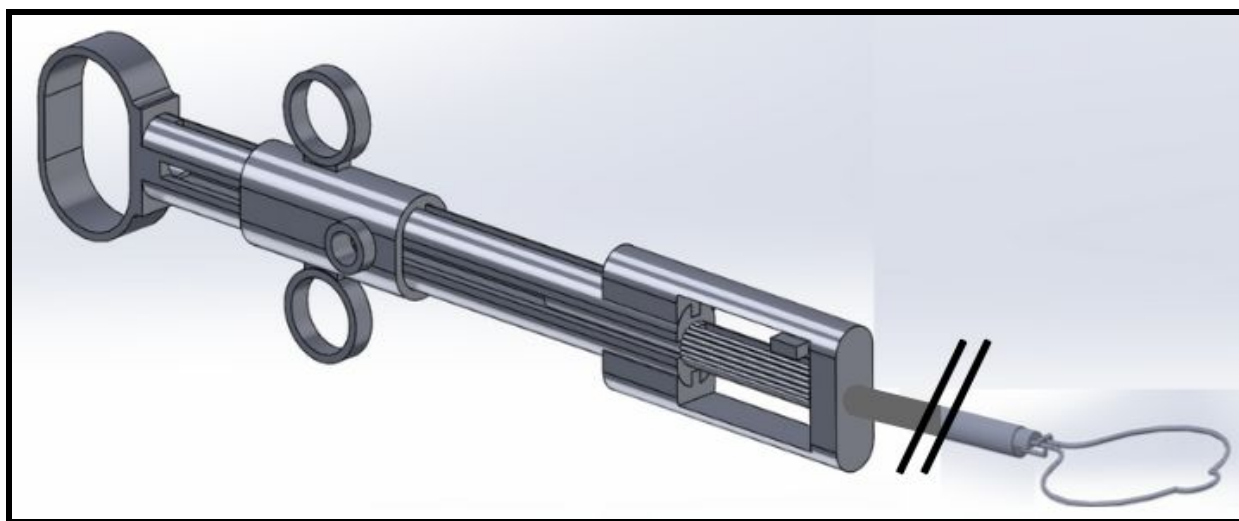
STORAGE INSTRUCTIONS

- The device must be stored in the original unopened packaging
- The device should not be used after the expiration date
- DO NOT store the device in places where it will become damaged, wet, or improperly sealed
- DO NOT store in an area with direct sunlight.
- DO NOT store in an area with above 80% humidity.
- Avoid environments that could potentially puncture the packaging
- Device should be stored in temperatures between -20 degrees celsius and 60 degrees celsius.

For additional information about the Tiger Snare and its use, please contact South Flex Medical.

Phone: 567-203-3717

Email: tigersnare@southflexmedical.com



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