

Piranha GI Instructions for Use

Aspiration Catheter

Device Description

The Piranha GI Aspiration Catheter is designed to be used in the esophagus to remove food blockages. It can also be used anywhere in the GI tract to aspirate blood clots. It is a 2.77 mm (8 Fr) max OD with a 2.23 mm min ID, 124 cm useable length single lumen braided biocompatible catheter with a shaped distal tip for coring through food impactions, or blood clots, as shown in Figure 1. The Piranha GI Aspiration Catheter has a molded, tapered handle that is a slip fit connection to hospital vacuum systems.

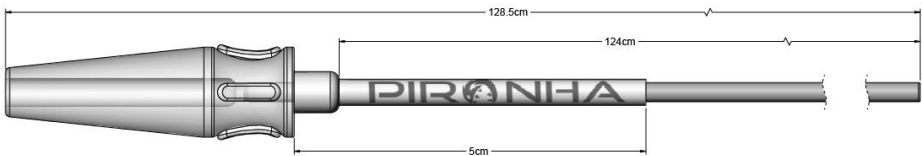


Figure 1. Piranha GI Aspiration Catheter

The Piranha GI Aspiration Catheter is designed to be used through the working channel (≥ 2.8 mm ID) of a standard endoscope. It is designed to extend outside the distal end of an endoscope by approx. 1" when fully inserted.

Indication for Use

The Piranha GI Aspiration Catheter is indicated for removal of food blockage / impaction in the esophagus. It is also indicated for aspiration of blood clots anywhere in the GI tract.

Contraindications

None known.

Warnings and Precautions

- The Piranha GI Aspiration Catheter should be used by a health care professional with adequate training in the use of the device.
- Federal (USA) law restricts this device to sale by or on the order of a health care professional.
- If package is damaged, DO NOT USE. Discard and open another package.
- Do not use if the device is kinked or damaged in any way.
- Single use only. DO NOT REUSE.
- Do not use if the Piranha GI Aspiration Catheter does not move freely through the working channel of a standard endoscope with a working channel ID of ≥ 2.8 mm.

Potential Complications

Complications may occur that are similar to all interventional procedures of this type, including:

- Perforation or laceration of a vessel
- Perforation or laceration of an organ, especially the esophagus, stomach, pharynx or hypopharynx
- Perforation of a viscus, particularly the esophagus
- Aspiration pneumonia
- Bleeding
- Hematoma
- Pain
- Infection
- Sepsis

Directions for Use

The following instructions provide technical direction and are not intended as a substitute for the physician's experience and judgment in treating a specific patient.

1. Following standard practices, introduce a standard endoscope to the level of the food impaction.
2. Remove the soft black biopsy cap from the biopsy channel of the endoscope.
3. Insert the Piranha GI Aspiration Catheter through the working channel of the endoscope until the GI aspiration catheter is visible through the distal end of the endoscope.

4. Once positioned in the endoscope, attach standard suction tubing to the Piranha GI aspiration catheter handle by pressing tubing firmly onto the handle. Adjust wall suction to its highest power setting.
5. Make sure that the catheter is not kinked prior to using. Any kink in the catheter will render the device inoperable.
6. Deliver 4-5 drops of water through the irrigation lumen of the endoscope. This will help saturate a food impaction and will also lubricate the Piranha catheter making it easier to aspirate food or blood clots.
7. The aspiration catheter, attached to suction, will then be employed to core pieces of the food impaction and suction the pieces as cored. The aspiration catheter will be advanced into the food to core pieces of food and then be withdrawn to allow suction. This process will be repetitively performed (coring and suctioning) as needed to clear the impaction. Repeat this step until food impaction is clear.
8. A similar process will be used to aspirate blood clots.
9. When the impaction, or blood clot, has been cleared, detach the vacuum from the Piranha GI aspiration catheter and remove from the endoscope.
10. Discard used Piranha GI device per facility requirements for medical waste disposal.

Packaging and Storage

The Piranha GI device is a non-sterile device. Keep dry and store in a cool, dry place.

Limited Warranty

Piranha Medical warrants that the Piranha GI device is free from defects in workmanship and materials prior to the stated expiration date. Liability under this warranty is limited to refund or replacement of the product, which has been found by Piranha Medical to be defective in workmanship or materials. Piranha Medical shall not be liable for any incidental, special, or consequential damages arising from use of the product. Damage to the product through misuse, alteration, improper storage, or improper handling shall void this limited warranty. No employee, agent, or distributor has any authority to alter or amend this limited warranty in any respect. Any purported alteration or amendment shall not be enforceable against Piranha Medical.

Symbols Legend



Catalog Number



Device Description



Batch Code



Prescription Use Only



Consult instructions for use



Keep dry



Keep away from sunlight



Use by date



Do not use if packaging is damaged



Do not reuse



Manufacturer



Device quantity



Piranha Medical
10351 Xylon Ave N, Suite 100
Brooklyn Park, MN 55445
Phone: 763-390-8864
Email: info@piranhamedical.com
www.piranhamedical.com