



Piranha LC Instructions for Use

Luminal Clearing Aspiration Catheter

Device Description

The Piranha LC Aspiration Catheter is designed to be used for pancreatic debridement and luminal clearance of necrotic tissue, blood or mucus. It can also be used anywhere in the GI tract or trachea/pulmonary tree to aspirate necrotic tissue, infected material, blood, mucus, or food. 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 necrotic tissue and fluid of a pseudo cyst, or through other infected material, blood, mucus, or food as shown in Figure 1. The Piranha LC Aspiration Catheter has a molded, tapered handle that is a slip fit connection to hospital vacuum systems.

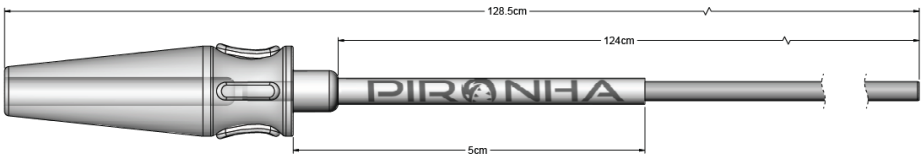


Figure 1. Piranha LC Aspiration Catheter

The Piranha LC can be used in conjunction with a flexible endoscope ($\geq 2.8\text{mm}$ ID) and a standard vacuum connection when used in the GI tract and introduced through the esophagus and stomach. It is designed to extend outside the distal end of an endoscope by approx. 1" when fully inserted.

The Piranha LC can also be used in conjunction with a flexible bronchoscope and standard vacuum connection when used in the lungs and introduced through the trachea and the bronchus.

Indication for Use

The Piranha LC Aspiration Catheter is indicated for used in pancreatic debridement and in the lumen for clearing of necrotic tissue and removal of pancreatic fluid collections. It is also indicated for aspirating and clearing infected material, blood, mucus, or food, anywhere in the GI tract or trachea/pulmonary tree.

Contraindications

None known.

Warnings and Precautions

- The Piranha LC 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.
- When using the Piranha LC Aspiration Catheter in conjunction with a standard endoscope, discontinue use if the Piranha LC Aspiration Catheter does not move freely through the working channel ID of ≥ 2.8 mm.
- When using the Piranha LC Aspiration Catheter in conjunction with a flexible bronchoscope, discontinue use if the Piranha LC Aspiration Catheter does not move freely through the working channel ID.

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 stomach, pseudo cyst, small intestine, or lung
- Perforation of a vascular vessels, particularly inside the pseudo cyst
- Aspiration pneumonia
- Bleeding
- Hematoma
- Pain
- Infection
- Sepsis

Directions for Use - Walled Off Necrosis Indication

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 EUS scope to the level of the pancreas and pancreatic cyst, fluid collection or area of necrosis
2. Remove the biopsy cap from the scope.
3. Insert the Piranha LC Aspiration Catheter through the working channel of the endoscope and advance until the aspiration catheter is visible through the distal end of the endoscope, approaching the collection.
4. Once positioned near the collection, attach standard wall suction tubing to the Piranha aspiration catheter handle by pressing firmly onto the handle. Adjust wall suction to its highest power setting.
5. If the collection contains solid or semi-solid material, deliver 4-5 drops of water through the irrigation lumen of the endoscope to lubricate the surface of the collection debris. This will soften the material and also lubricate the inner lining of the catheter.
6. The aspiration catheter, attached to suction, should then be advanced into the collection, coring material and then continue to core, in a to-and-fro manner, removing fluid and/or debris and intermittently allowing suction of the cored material.
7. Continue the to-and-fro coring and suctioning, until the material has been cleared to clinical satisfaction.
8. If the aspiration catheter becomes clogged, it can then be cleared by flushing air or water through the catheter. This can be achieved by disconnecting suction and attaching a 10 cc luer-lock syringe to the proximal portion of the catheter.
9. When the material has been cleared, detach the vacuum from the Piranha LC catheter and remove the device from the endoscope.

NOTE: Take great care not to kink the device. If it does get kinked, discard and use a new device.

Directions for Use - Mucus, Blood, Fluid Collection Removal Indication

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 therapeutic bronchoscope to the level of the trachea or any portion of the bronchial tree, then to the fluid, mucus or blood collection, or area of infected material.
2. Insert the Piranha LC Aspiration Catheter through the working channel of the bronchoscope and advance until the aspiration catheter is visible through the distal end of the bronchoscope, approaching the collection.
3. Once positioned near the collection, attach standard wall suction tubing to the Piranha aspiration catheter handle by pressing firmly onto the handle. Adjust wall suction to its highest power setting.
4. If the collection contains solid or semi-solid material, deliver 4-5 drops of water through the irrigation lumen of the endoscope to lubricate the surface of the collection debris. This will soften the material and also lubricate the inner lining of the catheter.
5. The aspiration catheter, attached to suction, should then be advanced into the collection, suctioning material and then continue to suction, in a to-and-fro manner, removing fluid, infected material, mucus, blood and/or debris and intermittently allowing aspiration of the material.
6. Continue the to-and-fro suctioning, until the material has been cleared to clinical satisfaction.
7. If the aspiration catheter becomes clogged, it can then be cleared by flushing air or water through the catheter. This can be achieved by disconnecting suction and attaching a 10 cc luer-lock syringe to the proximal portion of the catheter.
8. When the material has been cleared, detach the vacuum from the Piranha LC catheter and remove the device from the bronchoscope.

NOTE: Take great care not to kink the device. If it does get kinked, discard and use a new device.

Packaging and Storage

The Piranha LC device is a sterile device. Keep dry and store in a cool, dry place.

Limited Warranty

Piranha Medical warrants that the Piranha LC 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



EO Sterilization



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