



A-Tube™ Instructions for Use

Caution: US Federal law restricts this device to sale on or by the order of a physician.

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1. DEVICE DESCRIPTION

The AspireAssist A-Tube, when used as part of the AspireAssist, is designed to induce weight loss by reducing the amount of food entering the intestines from the stomach. With the AspireAssist, patients empty a portion of their stomach contents approximately 20 to 30 minutes after consuming each major meal. As a result, approximately 25-30% of the calories consumed in the meal are aspirated out of the body.

The A-Tube is introduced endoscopically through the mouth and placed percutaneously using the “pull” PEG technique. It should only be placed by those trained in endoscopic techniques and experienced in Percutaneous Endoscopic Gastrostomy (PEG) tube placement.

2. INDICATIONS FOR USE

The AspireAssist is intended to assist in weight reduction of obese patients. It is indicated for use in adults aged 22 or older with a Body Mass Index (BMI) of 35.0-55.0 kg/m² who have failed to achieve and maintain weight loss with non-surgical weight loss therapy. The AspireAssist is intended for a long-term duration of use in conjunction with lifestyle therapy and continuous medical monitoring.

3. CONTRAINDICATIONS

- Previous abdominal surgery that significantly increases the medical risks of gastrostomy tube placement
- Esophageal stricture, pseudo-obstruction, severe gastroparesis or gastric outlet obstruction, inflammatory bowel disease
- History of refractory gastric ulcers
- Ulcers, bleeding lesions, or tumors discovered during endoscopic examination
- Uncontrolled hypertension (blood pressure >160/100)
- History or evidence of serious pulmonary or cardiovascular disease, including acute coronary syndrome, heart failure requiring medications, or NYHA (New York Heart Association) class III¹ or IV² heart failure
- Coagulation disorders (platelets < 50,000, PT > 2 seconds above control or INR > 1.5)
- Anemia (hemoglobin <8 g/dL in women and <10 g/dL in men)

1 Class III: patients with marked limitation of activity and who are comfortable only at rest

2 Class IV: patients who should be at complete rest, are confined to bed or chair, and who have discomfort with any physical activity)

- Pregnant or lactating
- Diagnosed Bulimia or diagnosed Binge Eating Disorder (using DSM criteria)
- Night Eating Syndrome
- Chronic abdominal pain that would potentially complicate the management of the device
- Physical or mental disability, or psychological illness that could interfere with compliance with the therapy
- At high risk of having a medical complication from the endoscopic procedure or the AspireAssist weight loss program for any reason, including poor general health or severe organ dysfunction such as cirrhosis or renal dysfunction (GFR <60 mL/min/1.73 m², including Stage II or more severe chronic kidney disease).

4. WARNINGS

- The AspireAssist A-Tube is intended for single patient use only. Do not re-sterilize and/or reuse any part of the device on another patient.
- Do not continue the endoscopic procedure if transillumination cannot be identified. The selected site should be free of major blood vessels, viscera, and scar tissue to ensure safe passage of the A-Tube through the abdomen and incision site.
- Female patients with child-bearing potential should be counseled prior to installation that the A-Tube must be removed if she becomes pregnant. If the patient becomes pregnant at any time after the A-Tube is installed, the A-Tube should be removed. The safety of the AspireAssist has not been studied in pregnant women. During pregnancy, the expanding abdomen may cause tension on the Skin-Port potentially resulting in a buried bumper and an endoscopic or surgical procedure may be needed to remove the A-Tube.
- Use the AspireAssist A-Tube prior to the “Use By” date specified on the package.
- A-Tube removal must be performed under **direct endoscopic visualization**. The A-Tube should be removed via an endoscopic method (after removal of the Skin-Port), utilizing a snare to pull the tube out through the mouth. Avoid placing the snare around an aspiration hole. Grasp the A-Tube in between the holes to ensure that the entire circumference of the A-Tube is secured in the snare.
- The safety and effectiveness of the AspireAssist has not been

established in patients with:

- History of radiation therapy to the chest or abdomen
- Diabetes treated with insulin or sulfonylurea medications
- Hemoglobin A1C >9.5%
- Serum potassium < 3.8 mEq/L

5. CAUTIONS

- After opening the kit do not stretch or pull the A-Tube away from the dilator tip. This may put undue force on the tube and dilator tip connection causing separation of these components.
- Prior to endoscopic placement, the AspireAssist A-Tube should be examined for any anomalies and ensure that it is suitable for placement.
- If the package has been damaged or if the inner sterile pouch is opened outside the sterile field, the product must be considered non-sterile. Do not use or re-sterilize.
- Only physicians trained to perform percutaneous endoscopic gastrostomy (PEG) should place the AspireAssist A-Tube. Procedures requiring percutaneous needle introduction or endoscopy should not be attempted by physicians unfamiliar with the possible complications.
- If lubricants are required during A-Tube installation, ONLY use water-based lubricants. DO NOT use petroleum-based lubricants.
- When the AspireAssist A-Tube is endoscopically introduced into the body it should be manipulated under videoscopic observation. If resistance is met at any time during endoscope or A-Tube manipulation, determine the cause of the resistance before proceeding.
- After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.

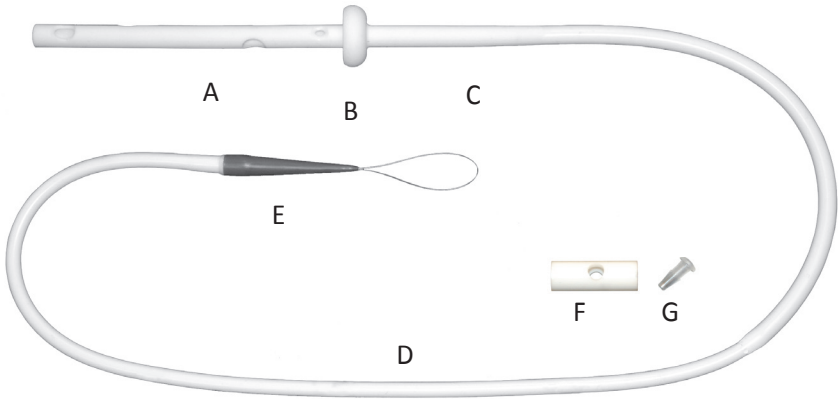
6. COMPLICATIONS

Complications may occur at any time during or after the procedure. The risks of endoscopic placement of the A-Tube are the same as endoscopic placement of a standard PEG tube and includes sedation complications, discomfort, sore throat, pain, abdominal bloating, indigestion, bleeding, infection, nausea, vomiting, hypoventilation, peritonitis, aspiration pneumonia, perforation, and death.

7. A-TUBE KIT COMPONENTS

All components of the AspireAssist A-Tube are for single use only. The A-Tube and External Bolster are sterilized with ethylene oxide gas and provided in a sterile pouch. Do not autoclave. The A-Tube is non-pyrogenic. Three plugs are provided non-sterile and do not require sterilization. A Patient Identification Card is also provided.

A-Tube, Bolster, and Plug. A) Gastric segment (15.2 cm x 30F) with five aspiration holes; B) Bumper (25mm diameter); C) Fistula segment that protrudes through skin (OD: 26F, ID: 6mm); D) Leader; E) Dilator with wire loop; F) External Bolster (not shown to scale), and Plug (not shown to scale).



8. A-TUBE INSTALLATION PROCEDURES

8.1 Preparation and Inspection Procedure

1. Administer intravenous antibiotic prophylaxis. Antibiotics (suggested regimen: 1 g of cefazolin sodium) should be given intravenously 30 to 60 minutes before A-Tube placement and a prescription for oral antibiotics for 24 hours (two doses) should be given after endoscopy (500 mg oral cephalexin every 12 hours). If the patient is allergic to cefazolin, clindamycin (900 mg intravenously) can be given followed by oral clindamycin therapy (300 mg p.o. every 8 hours) for 24 hours (three doses) after endoscopy, or vancomycin (1 gram intravenously) can be given before the procedure (no post endoscopy therapy). Ultimately, the antibiotic regimen used is left to the discretion of the physician inserting the A-Tube.
2. At the discretion of the physician or according to the institutions protocol:
 - a. Patients may have continuous oxygen saturation and cardiac

monitoring during the procedure.

- b. An anesthesiologist or nurse anesthetist may be present to manage anesthesia or if intubation is needed based on pre-sedation plan.
3. Open the outer box to reveal a pouch containing the A-Tube.
4. Peel the pouch open and carefully extract the A-Tube Assembly and outer bolster component.
5. Open a “Pull” Percutaneous Endoscopic Gastrostomy (PEG) Kit in similar fashion to provide the installation accessories needed to complete the procedure below. The gastrostomy tube included in the PEG Kit may be discarded.

8.2 Assembly and Insertion Procedure

1. Place the patient in a supine position and administer sedation. The specific choice for sedation and the decision to have an anesthesiologist or anesthetist present during the procedure is left to the discretion of the physician(s). A history of disordered breathing, obstructive sleep apnea, obesity-hypoventilation syndrome, and/or a thick neck with restricted movement are important risk factors; these should be considered when deciding on the type of sedation and the need for an anesthetist. Pulse oximetry and heart rate are monitored throughout the procedure.
2. Introduce the upper endoscope and perform a complete examination of the upper gastrointestinal (UGI) tract (esophagus, stomach, proximal duodenum). The tip of the endoscope is then positioned in the gastric body or antrum of the stomach.
3. Distend the stomach.
4. Determine the A-Tube site by: a) identifying a location on the abdominal wall where there is discrete transillumination of the endoscope light and b) pressing down on the site with one finger and visualizing discrete intragastric finger indentation through the endoscope. If transillumination cannot be identified, the patient may be repositioned to attempt to achieve transillumination. Alternative positions include the lateral position and reverse Trendelenburg position. If transillumination cannot be identified with repositioning, the procedure should be aborted.
5. Prepare abdomen with antiseptic solution and sterile drapes.
6. Anesthetize the skin site and subcutaneous tissue with lidocaine and bupivacaine.

7. Make a small (1 cm) skin incision using a scalpel.
8. Reconfirm discrete transillumination and finger indentation at the incision site.
9. Insert a snare through the endoscope and keep it in an open position at the insertion site.
10. Insert the guide wire needle (trocar) through the skin incision into the stomach and visualize the tip of the needle inside the stomach.
11. Introduce the guide wire through the guide wire needle (trocar), grasp the wire with a snare and remove the endoscope with the guide wire through the mouth.
12. Attach the A-Tube to the tip of the wire exiting the mouth. A lubricant is recommended on the exterior of the A-Tube to ease the introduction of the tube. Apply **ONLY** a water-based lubricant. To attach the A-Tube:
 - Insert the guide wire through the loop on the A-Tube.
 - Pull the tail of the A-Tube through the guide wire.
13. Tighten the guide wire by applying gentle tension at both ends and pull the A-Tube with the guide wire until the tip of the A-Tube emerges from the abdominal wall.
14. Pull out the A-Tube through the abdominal wall until more than 50 cm of tube are visible outside the abdominal wall. To alleviate tension, light abdominal pressure can be placed at the incision site while pulling the tube through the stoma site. *Note: If excessive resistance is met while exiting the abdominal wall, a scalpel may be used to enlarge the opening and reduce resistance.*
15. Reintroduce the endoscope and, under direct visualization, pull the tube further out until the internal bumper rests on the gastric mucosa without causing pressure on the mucosa. Document proper A-Tube position by taking a photograph of the site along the gastric wall.
16. Remove the endoscope.
17. Cut the external component of the tube to 10 cm - 15 cm from the abdominal wall (the cut must be within the thinner leader section of the tubing). Insert plug into external end of the A-Tube to prevent leaking of gastric contents. Place the External Bolster over the end of the A-Tube and slide it towards the skin until it is about 1cm from the skin (Note: the distance here is critical so it is not too tight when the patient is sitting).

18. Apply an antibiotic ointment to the gastrostomy site, dress the skin with gauze, and tape the excess tube to the patient's abdomen.

8.3 Post-Procedure

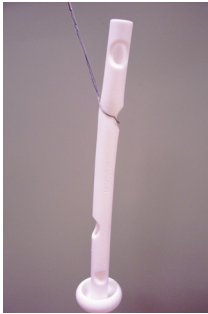
1. Perform an abdominal examination and record vital signs when the patient is awake and per institutional standards.
2. When the patient is fully awake and ready to get dressed, check the gastrostomy site while the patient is sitting. Make sure the bolster is in proper position (i.e. very close to the skin but without causing excessive pressure on the skin when patient is sitting, approximately 1 cm from abdomen).
3. If external bolster is too tight, adjust as needed to prevent pressure erosions. The bolster can be adjusted closer or farther away from the skin by sliding along the silicone tube. It should stay in place by friction.
4. Prescribe oral antibiotics and pain medication (if needed).
5. Fill out Patient Identification Card and provide to patient. Advise patient to keep card on his or her person (in wallet, for example) at all times in case of an emergency.
6. Warn the patient of the following:
 - Do not shower or take a bath for 2 days after A-Tube placement. Sponge wash by hand only.
 - Do not insert foreign objects between the bolster and the skin.
 - Do not clean the A-Tube with mechanical devices.
 - Do not manipulate the A-Tube at any time after installation. Excess tension or torque on the A-Tube can result in enlargement of the fistula tract resulting in gastric leakage, or retraction of the internal bumper resulting in tissue necrosis or migration into the fistula tract.
 - Notify physician if external bolster is too tight, so adjustments can be made as needed to prevent pressure erosions.
 - Do not expose the product to organic solvents (e.g. alcohol).

See *Clinician Guide* for complete post-operative care and Skin-Port attachment instructions.

9. INSTRUCTIONS FOR DEVICE REMOVAL

WARNING: A-Tube removal must be performed under **direct endoscopic visualization**. The A-Tube should be removed via an endoscopic method (after removal of the Skin-Port), utilizing a snare to pull the tube out through the mouth.

1. Place the patient in a supine position and administer sedation.
2. Introduce the endoscope, distend the stomach, and perform a complete examination of the upper gastrointestinal (UGI) tract (esophagus, stomach, proximal duodenum).
3. Insert a snare through the endoscope and navigate into the stomach.
4. Utilize the snare to grasp the A-Tube gastric segment near the end of the tube (1/3 or less of the distance to the internal bumper). Avoid placing the snare around an aspiration hole. Grasp the A-Tube in between the holes to ensure that the entire circumference of the A-Tube is secured in the snare.



Improper Placement



Correct Placement

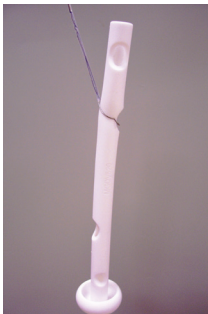
5. Remove the Skin-Port by cutting the tube externally with scissors.
6. Withdraw the tube through the esophagus. Make sure the bumper and excess tube do not fold over or overlap, which will increase the width of the extracted device and thereby increase the risk of gastroesophageal trauma.
7. Remove the scope and snare out of the mouth, pulling the A-Tube out in tow.

If the A-Tube has been in place for more than 12 months, the internal ostomy site should be treated with argon plasma coagulation (APC), irritated with a cytology brush, and then closed with an endoscopic clip or overstitch to enhance fistula closure. To minimize peristomal irritation from gastric leakage and to help closure, prophylactic treatment with a proton pump inhibitor is recommended until the stoma tract is healed completely. It is also recommended to instruct the patient to avoid over distending the abdomen and strenuous activities during the healing process, and always maintain good skin care practices at the stoma site. The A-Tube should be removed at about three years of use to ensure the integrity of the gastric portion of the tube and ease of removal.

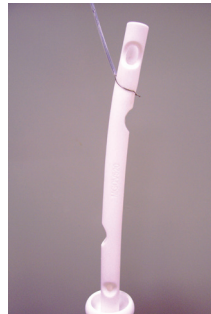
10. INSTRUCTIONS FOR DEVICE REPLACEMENT

The A-Tube should be replaced at about three years of use to ensure the integrity of the gastric portion of the tube and ease of removal.

1. Ensure the fistula is fully established and is not infected.
2. Introduce the endoscope and perform a complete examination of the upper gastrointestinal (UGI) tract (esophagus, stomach, proximal duodenum).
3. Distend the stomach with air.
4. Use the Valve Removal Tool to remove the valve of the Skin-Port, by aligning the legs of the Removal Tool with the feet of the valve, and pressing the Skin-Port and Removal Tool together. Leave the Skin-Port flange and sleeve in place.
5. Insert the guide wire through the Flange and Sleeve, and into the existing A-Tube into the stomach, until it exits the distal end of the A-Tube.
6. Use the snare to grasp the A-Tube gastric segment near the end of the tube at least 1/3 or less of the distance to the internal bumper. Avoid placing the snare around an aspiration hole. Grasp the A-Tube in between the holes to ensure that the entire circumference of the A-Tube is secured in the snare. Ensure that the guide wire is also captured with the A-Tube.



Improper Placement



Correct Placement

7. Remove the Sleeve from the A-Tube using forceps, then slide the Sleeve and Flange down the guide wire (away from the abdomen) to remove. Alternatively, the Skin-Port Flange and Sleeve can be removed by cutting the A-Tube with scissors, carefully cutting around the wire. Clean the skin around the fistula site with an alcohol swab.
8. Remove the endoscope and existing A-Tube (with the guide wire)














out through the mouth, while ensuring that a portion of the guide wire remains outside the abdomen. Make sure the bumper and excess tube do not fold over or overlap, which will increase the width of the extracted device and thereby increase the risk of gastroesophageal trauma.

9. Attach the new A-Tube to the tip of the wire exiting the mouth. If a lubricant is desired, apply **ONLY** a water-based lubricant to the exterior of the A-Tube. To attach the A-Tube:
10. Tighten the guide wire by applying gentle tension at both ends and pull the new A-Tube with the guide wire until the tip of the A-Tube emerges from the abdominal wall.
11. Grab the tip of the new A-Tube and pull the A-Tube out the gastric wall until more than 50 cm of tube are visible outside the abdominal wall.
12. Reintroduce the endoscope and, under direct visualization, pull the tube further out until the internal bumper rests on the gastric mucosa without causing pressure on the mucosa. Document proper A-Tube position by taking a photograph of the internal bolster along the gastric wall.
13. Remove the endoscope.
14. Cut the A-Tube at the thinner leader section of the tubing, and insert plug into external end. Slide the external bolster over the end of the A-Tube until it is about 1cm from the skin.
15. Once patient can safely maintain a **sitting position**, attach a Skin-Port to the external end of the A-Tube (See *Clinician Guide*).

11. MAGNETIC RESONANCE IMAGING (MRI)

The AspireAssist A-Tube and Skin-Port are composed of plastic and silicone, and do not contain any metal components. Both components are MR Safe. Magnetic Resonance Imaging (MRI) may be safely conducted with the A-Tube and Skin-Port in place.

12. SYMBOLS

	Sterilized using ethylene oxide		Caution, consult accompanying documents
	Catalog number		Consult instructions for use
	Do not reuse		Use by date
	Do not re-sterilize		Batch code
	Non-pyrogenic		Do not use if package is damaged.
	Manufacturer		Authorized representative in the European community
	MR Safe		

13. CONTACT

Aspire Bariatrics, Inc.
 3200 Horizon Drive, Ste 100
 King of Prussia, PA 19406 USA

www.aspirebariatrics.com
info@aspirebariatrics.com

Phone: +1 (610) 590-1577
 Fax: +1 (610) 279-1546

