Clinician Guide

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

SKIN-PORT QUICK REFERENCE

WARNING: During Skin-Port attachment, the **patient must be seated** when the Clamp Tray is attached (Step 1), to ensure that the Skin-Port is not too tight when the abdomen is compressed.

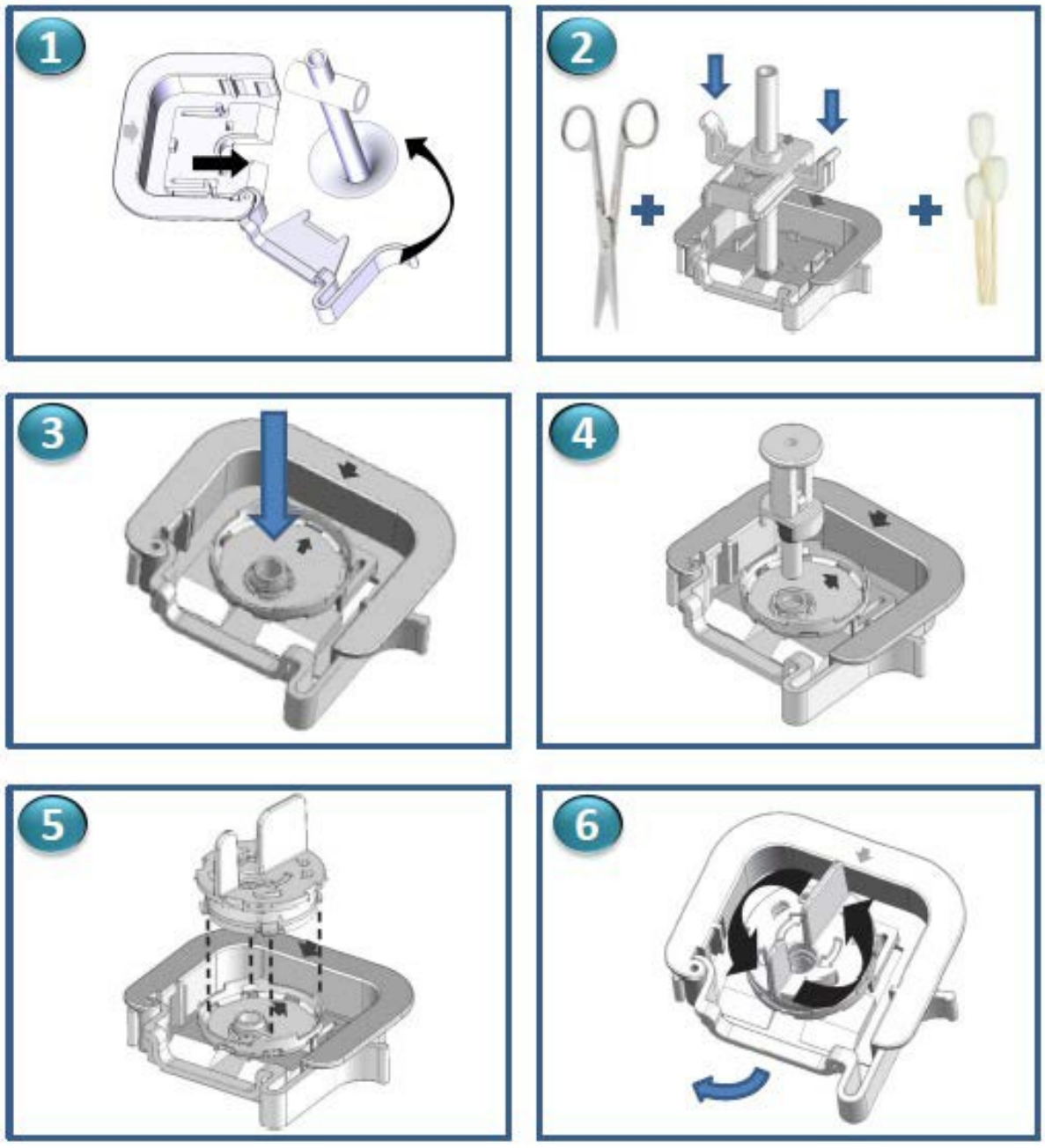


TABLE OF CONTENTS

1. DESCRIPTION

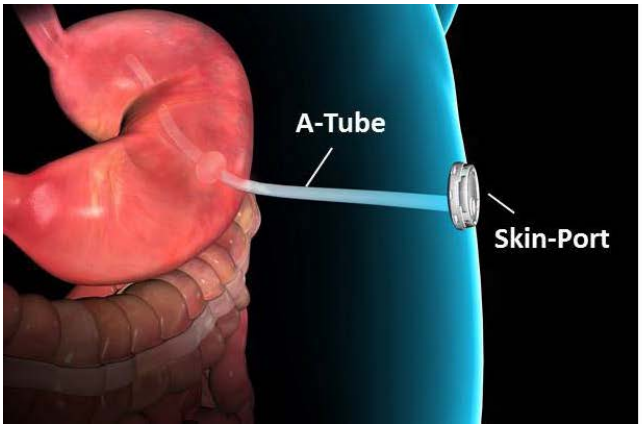
The AspireAssist induces weight loss by reducing the amount of food entering the intestines from the stomach. With the AspireAssist, patients aspirate (remove) a portion of their stomach contents approximately 20 to 30 minutes after consuming each meal. As a result, approximately 25-30% of the calories consumed in the meal are aspirated out of the body.

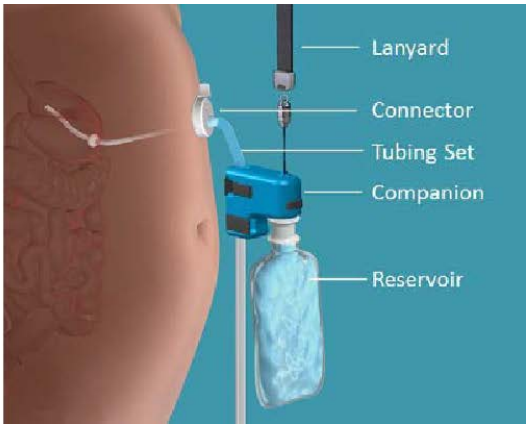
The AspireAssist device consists of two main sections. The components that remain attached to the patient for the duration of therapy are the A-Tube™ and Skin-Port™. The detachable components include the Companion and its accessories.

1.1 A-Tube and Skin-Port

The A-Tube is a 26Fr silicone Percutaneous Endoscopic Gastrostomy (PEG) tube, with a 15 cm gastric segment with five aspiration holes to allow stomach contents to enter. See *AspireAssist A-Tube Instructions for Use* for installation procedures.

The Skin-Port attaches to the external end of the A-Tube. The Skin-Port is a low-profile plastic valve that allows for connection to the detachable components of the system, and allows aspiration to commence.





1.2 Companion and Accessories

The detachable components of the device consist of the Companion and related accessories, which connect to the Skin-Port during the aspiration process. When the Connector locks onto to the Skin-Port, the Skin-Port valve opens and allows stomach contents to enter the tubing set and drain directly into the toilet. This process works by using gravity and does not contain electric mechanisms. The Connector has a counter that allows the patient to aspirate a maximum of 115 times before requiring a replacement Connector to continue aspirating. The patient can infuse water into the stomach to loosen food particles by squeezing the Reservoir. See *AspireAssist Patient Guide* for detailed instructions.

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/m^2 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 III[1] or IV[2] heart failure
- Coagulation disorders (platelets < 50,000, PT > 2 seconds above control or INR >1.5)
- Anemia (hemoglobin <8.0 g/dL in women and <10 g/dL in men)
- 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 m^2, including Stage II or more severe chronic kidney disease)

4. WARNINGS

- Female patients with childbearing 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 before the Skin-Port becomes tight

[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)

due to weight gain or abdominal expansion. 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. See **Section 16.3, Pregnancy**.

- Patients must be regularly monitored by a physician for the duration of therapy to prevent serious medical complications or death.
- The Skin-Port is intended for single-patient use only. Do not sterilize and/or reuse the Skin-Port components on another patient. Reuse of the Skin Port on another patient could result in infection or transfer of disease.
- Excess tension on the A-Tube should be avoided as it may result in dislodgement or misalignment of the internal bumper from its position in the stomach and may lead to excessive gastric leakage or peristomal irritation.
- The Skin-Port must not be so tight that the A-Tube bumper exerts pressure on the stomach wall, as this can lead to buried bumper, ulceration or A-Tube migration into the fistula tract. Assess the patient in supine and sitting positions to determine whether Skin-port is too tight.
- During Skin-port attachment, the patient must be seated when the Clamp Tray is attached, to ensure that the Skin-Port is not too tight when the abdomen is extended as this can lead to buried bumper, ulceration or A-Tube migration into the fistula tract and require treatment or an additional procedure to remove the A-Tube.
- In case of A-Tube occlusion that requires manual removal with an endoscopy brush, extreme caution should be exercised as the brush can exit one of the aspiration holes and damage the gastric mucosa. Use endoscopy brushes only; wires with sharp ends or other devices with sharp protrusions should not be used.
- The patient's mental health history should be thoroughly evaluated for evidence of past dysfunctional eating behaviors and potential triggers for eating disorders. This evaluation helps assure that patients prone to these issues are identified and potentially excluded from AspireAssist therapy.
- The integrity of the skin surrounding the stoma should be examined regularly for signs of irritation, infection, or tissue degradation. If severe erosion occurs, A-Tube removal may be required to facilitate healing. See **Section 15.1 Stoma Management** for treatment recommendations.
- 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

- Prior to attachment to the A-Tube, confirm that the all components of the Skin-Port and Skin-Port Installation Tool Kit are available for use.

- If there is any leakage between the Skin-Port and A-Tube after Skin-Port installation, remove the Skin-Port and reinstall it.
- 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. POTENTIAL ADVERSE EVENTS

Most potential adverse effects associated with the AspireAssist include events associated with any conventional gastrostomy tube placement including those related to the placement procedure and stoma related care. Other potential effects that are unique to the AspireAssist are associated with the therapy itself including electrolyte abnormalities, eating behaviors, and concomitant medications.

The risks of endoscopic placement of the A-Tube are similar to endoscopic placement of a standard Percutaneous Endoscopic Gastrostomy (PEG) tube and includes sedation complications, discomfort, sore throat, pain, abdominal bloating, indigestion, bleeding, infection, nausea, vomiting, hypoventilation, peritonitis, aspiration pneumonia, perforation, and death.

Risks related to the stoma include: abdominal discomfort/pain, peristomal skin irritation/ inflammation, erythema and granulation tissue, peristomal leakage and/or bleeding, stoma site infection, buried bumper syndrome, persistent fistula after tube removal, and skin induration.

Risks related to the aspiration process (e.g. the process of removing a portion of each meal) include occasional indigestion, nausea, vomiting, constipation, and diarrhea.

7. CLINICAL RESULTS

The PATHWAY study was a 10-center, randomized, controlled, open-label, 52-week trial to evaluate the the safety and efficacy of the AspireAssist in treating obesity. Eligible subjects were randomized in a 2:1 (treatment: control) ratio to treatment with the AspireAssist (including Lifestyle Therapy) or Control (Lifestyle Therapy only) program. AspireAssist subjects who achieve at least 10% total body weight loss from baseline assessed at each annual visit are given the option to continue in the study for an additional year, up to a total of five years.

Subjects in both arms received lifestyle counseling sessions once per month for the first 12 months of the study. Individual counseling session lasted 20-30 minutes, and group sessions lasted 60 minutes.

The primary analysis population for this trial was the modified intent-to-treat (mITT) population, which included all enrolled subjects in the trial. Enrolled subjects included any subjects that started any treatment (AspireAssist or Control). Subjects who were randomized but did not receive treatment were excluded from this analysis. The Multiple Imputation method was applied to missing endpoint data.

7.1 Primary Efficacy Endpoints

The first co-primary efficacy endpoint objective was to demonstrate a mean difference of at least 10% Excess Weight Loss (EWL) between the AspireAssist and Control arms (super-superiority), as measured by the Body Mass Index (BMI) method at 52 weeks of therapy.

The second co-primary efficacy endpoint objective was to demonstrate at least a 50% responder rate in the AspireAssist arm at 52 weeks, as defined by %EWL of at least 25% as measured by the BMI method.

7.2 Safety Outcomes

The incidence of procedure-related, device-related, and therapy-related adverse events were measured, as well as the incidence of device related, or unrelated, serious adverse events, including unanticipated adverse device effects. In addition, the development of adverse eating behaviors was assessed.

7.3 Subject Accountability

207 subjects were randomized with 171 subsequently enrolled in the PATHWAY study. In the AspireAssist group, 137 subjects were randomized, of which 26 withdrew or were excluded before starting the study, yielding 111 modified intent-to-treat (mITT) enrolled AspireAssist subjects. In the Control group, 70 subjects were randomized, of which 10 withdrew from the study before enrolling, yielding 60 enrolled Control subjects. **Table 7-1** shows the baseline demographics of the enrolled population.

Table 7-1: Baseline Demographics for AspireAssist and Control Groups

Characteristic	AspireAssist N=111	Control N=60
Gender		
Male	15 (13.5%)	7 (11.7%)
Female	96 (86.5%)	53 (88.3%)
Age at Screening (years)	42.4±10.0	46.8±11.6
Race		
Caucasian	74 (66.7%)	42 (70.0%)
African American	33 (29.7%)	17 (28.3%)
Other	4 (3.6%)	1 (1.7%)
Ethnicity		
Hispanic	11 (10.0%)	11 (18.3%)
Not Hispanic	100 (90.0%)	49 (81.7%)
Height (cm)	166.3±8.2	165.7±8.0
Weight (kg)	116.9±21.2	112.8±16.1
BMI (kg/m^2)	42.0± 5.1	40.9 ± 3.9

Note: Data is presentated as n (%) for categorical variables, and as mean ± standard deviation for continuous variables.

Of those 111 AspireAssist subjects who enrolled in the study, 29 withdrew from the study prior to 52-weeks. Of these 29 subjects, 5 subjects moved out of the area, 1 subject had unrelated health issues, 22 subjects withdrew due to subject decision, and 1 subject withdrew due to an adverse event (abdominal discomfort) as described in the table below.

Table 7-2: AspireAssist Subject Withdrawals

# of Subjects	Reason for withdrawal
5	Subjects moved out of state; no site near new location.
1	Medical reasons unrelated to therapy
2	Family Issues caring for children resulting in lack of time or discomfort from the A-Tube due to a young child tugging on the tube
15	Lack of time to aspirate, no motivation
3	Nausea, Discomfort, Lack of time or motivation
1	Subject and spouse felt device interfered with intimacy
1	Poor Results Lack of Weight Loss Efficacy
1	Abdominal discomfort, subject withdrew because of pain. Unwilling to take medication to relieve pain.

Of the 60 Control subjects who enrolled in the study, 29 withdrew prior to 52-weeks. The primary reasons were lack of time for study visits, unhappy with group assignment, and unrelated health issues. One Control subject withdrew after the first visit, and therefore lacks sufficient data for multiple imputation. As a result, this subject is excluded from endpoint analyses using multiple imputation.

7.4 Clinical Study Results

Co-Primary Efficacy Endpoints

In the mITT analysis, the AspireAssist group acheived 31.5% EWL at 52 weeks, compared to 9.8% in the Control group. The observed difference between the two groups was 21.7 percentage points (95% CI, 15.3% to 28.1%), which exceeds the super-superiority margin of 10% (p=0.0083), so this co-primary efficacy endpoint was met.

Table 7-3a: Summary of Co-Primary Efficacy Endpoint #1

Analysis Population	N (Control)	N (AspireAssist)	Mean %EWL (Control)	Mean %EWL (AspireAssist)	Difference in Mean %EWL (95% CI)	P value (10% Delta)
Modified Intent-to-Treat	59*	111	9.8	31.5	21.7 (15.3, 28.1)	0.0083
Per-Protocol**	31	82	13.0	37.2	24.2 (15.5, 32.9)	0.0038

*One control subject withdrew after the first visit, and therefore lacks sufficient data for multiple imputation.
**Includes all treated subjects who completed the scheduled follow-up visits up to and including 52 weeks.

For the second co-primary efficacy endpoint, 56.8% (95% CI, 49.0% to 64.5%) of the AspireAssist subjects were responders, using the mITT population. Therefore, the study did not meet the 95% lower bound confidence interval for the second co-primary endpoint target of 50% of subjects with >25%EWL. In the Control group, 15.3% were responders (95% CI, 8.2% to 25.1%).

Table 7-3b: Summary of Co-Primary Efficacy Endpoint #2

Analysis Population	Group	Number of subjects	Number of Responders	Responder Rate (95% CI)	P value (50% Responder Rate)
Modified Intent-to-Treat	AspireAssist	111	63	56.8% (49.0, 64.5)	0.0754
	Control	60	13	22.0% (12.1, 29.9)	1.0000
Per-Protocol*	AspireAssist	82	56	68.3% (58.8, 76.7)	0.0002
	Control	31	8	25.8% (13.5, 41.8)	0.9990

*Includes all treated subjects who completed the scheduled follow-up visits up to and including 52 weeks.

Secondary Efficacy Endpoints

Secondary outcomes at 52 weeks were: 1) Mean percent absolute weight loss in the AspireAssist group compared to the Control group, 2) proportion of subjects who achieve ≥10% absolute weight loss in the AspireAssist group compared to the Control group, 3) mean percent change serum lipids (triglyceride, HDL-cholesterol and LDL-cholesterol concentration) in the AspireAssist group compared to the Control group; 4) mean percent change in systolic and diastolic blood pressures in the AspireAssist group compared to the Control group; 5) "Impact of Weight on Quality of Life" (IWQOL) questionnaire; 6) change in mean hemoglobin A1C (only subjects with Type 2 diabetes at baseline), 7) percent procedural success (defined as successful endoscopic placement of the A-Tube) in all subjects undergoing endoscopy; and 8) mean percent change in medications. The study was not powered for assessment of changes and did not include a pre-determined endpoint for factors associated with health improvements; however, data were collected to measure changes in comorbid conditions and quality of life. Results suggest that there were small, but not statistically significant, improvements in comorbid parameters for diabetes, hypertension, hyperlipidemia, and quality of life from baseline to 52 weeks in the treatment and control groups. These small improvements were likely attributable to factors shared by the AspireAssist group and the Control group, such as Lifestyle Therapy.

Table 7-4: Summary of Secondary Efficacy Weight Loss Endpoints 1 and 2 (mITT)

Parameter	Unit of Measure	Control	AspireAssist	Difference (AspireAssist – Control)	Difference (95% CI)
% TBL	Mean Percent TBL	3.6	12.1	8.6	6.2, 10.9
≥10% TBL	Percent of Subjects	22.1	58.6	36.5	24.84, 48.21

For secondary endpoint 7, out of 114 endoscopies attempted in 112 subjects, there were 111 successful A-Tube placements. Excluding the two aborted procedures in subjects who had contraindications for A-Tube placement, there were 111 successful A-Tube placements in 112 endoscopy attempts, yielding a

procedure success rate of 99%. In one subject, adequate transillumination could not be obtained initially and the procedure was aborted; however, in a subsequent procedure transillumination was successfully obtained by repositioning this subject.

The 8th secondary endpoint is the mean change in medications from baseline. The total number of medications taken at baseline for the three comorbidities identified as secondary endpoints: hypertension, dyslipidemia and Type 2 diabetes for subjects that have completed 52 weeks were evaluated. Over the course of therapy, both the AspireAssist group and the Control group saw a decrease in the total number of medications and the average number of medications per subject. There were also several subjects who stopped all medication for a specific comorbidity.

Safety and Adverse Events

Within the first 52 weeks, there were five Serious Adverse Events (SAEs) related to the device or procedure, involving 4 out of 111 AspireAssist subjects, yielding a related-SAE rate of 3.6% (95% CI: 0.1%-7.1%).

Table 7-5: Device, Procedure, or Therapy-Related Serious Adverse Events

Adverse Event	n (%) Subjects	N Events
SAEs Related to the Device		
A-Tube Replaced	1 (0.9%)	1
SAEs Related to the Procedure		
Peritonitis (mild pneumo-peritoneum without abscess)	1 (0.9%)	1
Abdominal pain post-procedure	1 (0.9%)	2
Non-bleeding pre-pyloric ulceration	1 (0.9%)	1*

* Event recorded at week 53

There was one SAE after the 52 week study period which involved one subject who experienced a small opening in the tissue just superior to the A-Tube stoma site.

Considering all SAEs, including those not related to the device, or procedure, there have been 16 SAEs reported over the 52 week study period, involving 12 AspireAssist subjects (13 events) and 3 control subjects (3 events).

Table 7-6 describes all adverse events (AEs) which occurred in ≥ 5% of AspireAssist subjects over the 52 weeks study period. The most common adverse events were similar in nature to those with standard PEG tube placement, and include peristomal granulation tissue, pain, abdominal discomfort, and nausea/vomiting. As shown in **Table 7-6**, the majority of events, with the exception of granulation tissue, were acute and resolved within the first 7 days. These events were also generally mild in severity with only two events described by the subject as severe.

Table 7-6: Most Common Adverse Events Related To Therapy, Device, or Procedure

AE Category	N (%) N=111	Onset	Duration				Severity** Number of events total/N (%)	Number of events occurring within 7 days/N (%)
		Mean Median Range (days)	Mean Median Range (days)	N (%) Onset ≤7 days	N (%) >14 days	N (%) >30 days	Mild Moderate Severe	Mild Moderate Severe
Peristomal Granulation Tissue	45 (40.5)	118.3 79 19-380	312.5 131 0-787	0 0 0	45/45 (100.0)	40/45 (88.9)	41/45 (91.1) 3/45 (6.7) 1/45 (2.2)	0 0 0
Pain, abdominal ≤ 4 weeks after A-Tube placement	42* (37.8)	0.26 0 0-3	19.3 13 1-160	42/42 (100.0)	12/42 (28.6)	4/42 (9.5)	18/42 (42.8) 24/42 (57.1) 1/42 (2.4)	17/42 (40.5) 24/42 (57.1) 1/42 (2.4)
Peristomal bleeding, discharge, inflammation, irritation	34 (30.6)	101 52.5 0-383	68.1 31 3-503	10/34 (34.5)	0/34 (0)	0/34 (0)	29/34 (85.3) 5/34 (14.7) 0	9/34 (26.5) 1/34 (2.9) 0
Nausea/ Vomiting	21 (18.9)	45.2 0 0-366	10.1 3 0-108	15/21 (71.4)	1/21 (4.8)	1/21 (4.8)	11/21 (52.4) 10/21 (47.6) 0	8/21 (38.1) 7/21 (33.3) 0
Abdominal discomfort, intermittent	21 (18.9)	20.1 1 0-147	44.1 13 3-297	16/21 (76.2)	5/21 (23.8)	4/21 (19.0)	15/21 (71.4) 6/21 (28.6) 0	11/21 (52.4) 5/21 (23.8) 0
Other, Peristomal bacterial infection/ possible infection	16 (14.4)	4.2 4 1-7	12.6 10 7-45	13/16 (81.3)	2/16 (12.5)	1/16 (6.3)	15/16 (93.8) 1/16 (6.3) 0	12/16 (75.0) 1/16 (5.3) 0
Pain, abdominal > 4 weeks after A-Tube placement	9 (8.1)	163 94 32-376	49.4 28 1-136	0 0 0	9/9 (100.0)	9/9 (100.0)	3/9 (33.3) 6/9 (66.7) 0	0 0 0
Change in bowel habits	5 (4.5)	1.3 0.5 0-4	121.3 11 4-459	4/5 (80.0)	1/5 (20.0)	1/5 (20.0)	5/5 (100.0) 0 0	4/5 (80.0) 0 0

*One subject reported 2 AEs for pain, **Severity: *Mild*: symptoms tolerated w/ some difficulty; *Moderate*: interference with normal daily activities; *Severe*: requires hospitalization

A total of 235 adverse events were reported by 94 subjects during study year one. Seven of these were considered unrelated SAEs, leaving a total of 228 related AEs reported by 93 subjects. As shown in **Table 7.7**, a total of 228 related adverse events (including the 5 SAEs described in **Table 7.5**), have been reported by 93 (83.8%), AT subjects. On average, each AT subject has experienced 2.5 related adverse events within the first 52-weeks.

Table 7.7 Adverse Events ≤ 52weeks

Event description	# of events	# of subjects	% of subjects (N=111)
Peristomal granulation tissue	45	45	40.5%
Pain, abdominal ≤ 4 weeks after A-Tube placement	43	42	37.8%
Abdominal discomfort, intermittent	21	18	16.2%
Nausea/vomiting	21	20	18.0%
Peristomal irritation	21	19	17.1%
Other: Peristomal bacterial infection confirmed/Possible infection (symptoms not confirmed by culture, antibiotic prescribed in most cases)	16	15	13.5%
Hypokalemia	9	4	3.6%
Pain, abdominal >4 weeks after A-Tube placement	9	9	8.1%
Other: dyspepsia (acid reflux, heartburn, hiccups, belching)	7	7	6.3%
Peristomal inflammation	6	6	5.4%
Peristomal discharge	5	5	4.5%
Change in bowel habits (Constipation/diarrhea/loose stools)	5	5	4.5%
Accidental A-Tube dislodgement or trauma	3	3	2.7%
Peristomal bleeding	2	2	1.8%
Fungal infection, peristomal	2	2	1.8%
Miscellaneous single events*	13	13	0.9%
TOTAL related AEs/AADEs (for 111 AT subjects)	**228**	**93****	**83.8%**

Others: (1) A-Tube Replacement, (1), broken front tooth veneer, (1) buried bumper, (1) ecchymosis, (1) fever, (1) free-air in abdomen (anticipated after tube placement), (1) peristomal ulceration, (1) persistent fistula, (1) worsening bilateral leg edema, (1) pain (hand), (1) pain (substernal discomfort), (1) peritonitis, (1) stomach spasm. Each event occurred once in one subject, so the % of subjects experiencing each event is 0.9%. **** Totals do not add as some subjects had more than one adverse event

Table 7-8 describes adverse events which occurred after 52 weeks and are generally similar in nature to the adverse events prior to 52 weeks. The last three events include one subject who felt that she was overeating in the evening, one subject with a mild ulceration which did not require treatment, and the persistent fistula is reported above as the post 52 week SAE where there was a small tissue opening which developed above the stoma site.

Table 7-8 Related AEs >52-weeks

Event description	Number of events	Number of subjects (%) N=60*
Peristomal granulation tissue	3	3 (2.7)
Pain, abdominal >4 weeks after A-Tube placement	3	3 (2.7)
Peristomal irritation	1	1 (0.9)
Abdominal discomfort, intermittent	1	1 (0.9)
Bacterial infection, peristomal	1	1 (0.9)
Hypokalemia	1	1 (0.9)
Other: eating disorder NOS	1	1 (0.9)
Other: gastric ulcer	1	1 (0.9)
Persistent fistula	1	1 (0.9)
Total	**13**	13 (21.7)

*data is calculated based on the n=60 who continued therapy after 52 weeks

7.5 Aspire Pathway Post Approval Study Summary

Study Design

The Pathway Post Approval Study is a multicenter, single-arm prospective, active surveillance study designed to gather long-term data on the incidence, duration, and severity of adverse events, weight loss, compliance with AspireAssist therapy, impact of AspireAssist therapy on eating behavior and the effectiveness and safety outcomes after device removal. This study followed patients from the PATHWAY pivotal study for five years post implantation who maintain ≥ 10 % absolute weight loss (relative to baseline) at each annual visit. Patients that had the device explanted were followed for two years post device explant.

Study Population

At the end of the Pathway study there were 31 patients who agreed to participate in the extended follow up PAS. Of these 31 patients, 30 had the A-Tube in place and were undergoing active therapy, while 1 was in post-explant follow-up.

Data Source

De-identified data is sourced from the electronic Case Report Forms completed by clinical site staff to document study visits, physical and psychological examinations and laboratory data.

Key Study Endpoints

Safety Endpoints

While the device is implanted, the safety of the device is evaluated by: 1) The incidence of device-related, procedure-related, and therapy-related adverse events; 2) The incidence of device-related or unrelated

serious adverse events, including unanticipated adverse device effects; and 3) Development of adverse eating behaviors as measured by the Eating Disorder Examination (EDE) and the Questionnaire on Eating and Weight Patterns – Revised (QEWP-R).

Efficacy Endpoints

The efficacy of the device while implanted is assessed by percent excess weight loss (%EWL) and total body loss (%TBL). Other efficacy study endpoints while the device is implanted include the change in obesity-related comorbidities (blood pressure, lipid levels, triglycerides, HbA1c) and change in medications.

Total number of Enrolled Study Sites and Subjects, Follow-up Rate

Seven (7) sites participated from the original Pathway study. Those 7 sites had 31 patients who were enrolled. 30 were actively participating in therapy and 1 patient was in post explant follow-up.

Study visits and length of follow-up

During years 2 through 5 there were quarterly visits (every 13 weeks) for medical monitoring, which includes metabolic, psychological and physical assessment.

In patients where the A-Tube is explanted, follow-up occurred months 2, 4 and 6 or until the stoma was healed. Then additional follow up at year one and year two post explant for physical assessment and patient satisfaction.

Summary of the Post-Approval Study Results

Final safety findings

Over the course of 5 years there were no new or unanticipated adverse events. In years 2 through 5 there was a significant reduction in adverse events. This supports the original Pathway study results which demonstrated that the majority of issues were a result of initial A-Tube placement. In the Post Approval Study there were two reports of gastric ulcer, gastric erosion. It appeared that the A-Tube had rotated towards the pylorus. This is an infrequent event and can be detected by a significant decrease in aspiration flow. Further, A-Tube position can be verified by x-ray to confirm. The most frequent issue with 4 occurrences are persistent fistulas. This is anticipated in subjects who have a tube in place for more than a year. Aspire provides recommendations for stoma tract preparation to minimize the potential for this event, see Section 18.

Adverse Events: The following table describes the adverse events which occurred during the remaining 4 years of the PAS.

Adverse Events

Description	**n Patients**	**N Events**
Related to the Device		

Gastric ulcer noted during A-Tube replacement	1	1
Cellulitis related to inadvertent trauma to A-Tube	1	1
Peristomal inflammation	1	1
Persistent fistula	4	4
Gastric and duodenal ulcers and erosions	1	1
Bacterial infection, peristomal	1	1
Peristomal leakage	1	1
Related to the Procedure		
Superficial mucosal tear, occurred during A-tube replacement	1	1
Related to the Therapy		
None	0	0

Serious Adverse Events: There was one serious adverse event in which the patient dislodged the A-Tube requiring removal earlier than planned.

Eating Disorders: No patients reported or demonstrated any adverse eating behaviors as measured by the Eating Disorder Examination (EDE) and the Questionnaire on Eating and Weight Patterns – Revised (QEWP-R).

Final effectiveness findings

The efficacy of the device is assessed by percent excess weight loss (%EWL) and total body loss (%TBL). Other efficacy study endpoints include the change in obesity-related comorbidities (blood pressure, lipid levels, triglycerides, HbA1c) and change in medications. As shown in the tables below there is improvement in most measures from year one to year 5. As anticipated, there is a period of therapy exhaustion around year three where subjects seem to lose motivation and as a result efficacy improvements stall. Aspire is aware of this potential issue and recommends subjects take a break from therapy for a short time rather than having the tube removed to determine whether the subject is able to maintain their weight loss through lifestyle changes they have implemented. See section 11.5.

%EWL

Year	N	%EWL	Std Dev
1	31	51.2	24.7
2	31	45.2	26.0
3	22	44.7	29.7
4	15	50.8	31.9
5	10	64.8	28.2

%TBL

Year	N	%TBL	Std Dev
1	31	19.1	8.0
2	31	16.9	8.9
3	22	16.6	10.5
4	15	18.7	11.7
5	10	24.3	10.46

The following tables provide data for the primary co-morbidities hypertension, and dyslipidemia. Note that subjects with uncontrolled comorbidities were excluded from the study.

Change in Blood Pressure

		Baseline	Year 1	Year 2	Year 3	Year 4	Year 5
Systolic Blood Pressure (mmHg)	n	31	31	31	21	15	10
	Mean	124.8	121.7	122.2	124.4	116.3	117.8
	Std. Dev.	15.5	14.6	13.8	15.7	12.4	9.9
Diastolic Blood Pressure (mmHg)	n	31	31	31	21	15	10
	Mean	80.9	76.8	76.9	77.6	77.0	73.7
	Std. Dev.	10.0	10.2	11.1	10.0	7.5	6.4

Change in Lipids and Triglycerides

		Baseline	Year 1	Year 2	Year 3	Year 4	Year 5
HDL-C	n	31	31	31	22	15	10
	Mean	54.4	60.0	60.4	58.6	59.0	62.4
	Std. Dev.	15.3	15.4	14.1	12.8	15.2	15.1
LDL-C	n	31	31	31	22	15	10
	Mean	114.0	102.9	107.2	112.7	113.5	125.3
	Std. Dev.	28.7	26.8	28.0	33.9	22.5	23.8
Trigs	n	31	31	31	22	15	10
	Mean	151.2	119.5	121.3	127.0	127.4	106.5
	Std. Dev.	96.8	75.9	74.5	63.9	78.2	60.0

Post Explant Follow-up Results

There were 20 subjects who had the A-Tube removed during the Post Approval Study, and one additional subject who was in post explant follow-up when they enrolled. 7 subjects completed the first year post explant follow-up and 3 subjects completed the year 2 post explant follow-up. It is difficult to draw any conclusions with so few data points. In general, all subject stoma sites were healed, there was a decrease in weight loss over the two years. There were no indications of any eating disorders over the period. There was an impact of Weight on Quality of Life Questionnaire (IWQOL). The IWQOL score demonstrated an improvement of 19% over baseline indicating that subjects continued to have an improved sense of wellbeing two years after leaving therapy.

Study Strength and Weaknesses

The strengths of the Post Approval Study are the long term safety and effectiveness data which is consistent with the one year study data from the PATHWAY clinical trial. There were no unanticipated long term issues, and the adverse events which occurred were anticipated and consistent with what has been seen for the therapy as well as in standard PEG tube usage. The frequency, severity and duration of events in years 2 through 5 were markedly less than seen in the first year of the study. This confirms that

most issues with the therapy are related to the procedure used to place the A-Tube, primarily abdominal pain and discomfort. The data also demonstrate continued effectiveness of the therapy by sustained weight loss and modest improvements in comorbidities over the duration of the study.

The primary weakness is the small number of subjects remaining in the study at the end of 5 years. There were 20 subjects who withdrew from therapy over the course of the study leaving 10 subjects who completed the 5 years. Of the 20 subjects who withdrew, 7 completed the 1 year post explant visit, 3 completed the 2 year post explant visit.

8. PREOPERATIVE PATIENT COUNSELING

Before A-Tube placement, patients must be fully aware of the requirements of the therapy. The following are recommended questions for discussion with the patient:

- Can you realistically commit 10-15 minutes to aspirate approximately 20-30 minutes after each major meal, typically three times per day?
- Does your schedule, work environment, or home commitments allow you to excuse yourself to aspirate about 20 to 30 minutes after eating?
- Where will you aspirate? Please carefully consider the location and types of restrooms available to you throughout the day.
- If necessary, would you be comfortable aspirating in a public or shared restroom?
- Do you have people in your life to support you in your weight loss journey?
- Would you be open to participating in local support groups with other AspireAssist patients?
- Will you be comfortable with having a low-profile Skin-Port on your abdomen for as long as you are continuing therapy? Consider situations such as wearing a swimsuit or during intimacy.
- If you have a partner, is your partner comfortable with you having a Skin-Port?
- Are you willing and able to chew your food extremely carefully, to prevent food from clogging during aspiration? Consider the additional time required to eat your food very slowly and carefully. If you have dentures, are they properly fitted?
- Are you committed to making gradual lifestyle changes during the course of therapy, including healthier food/drink choices, smaller portion sizes, limited snacking, and increased physical activity?
- Can you commit to the time and travel requirements to make all scheduled follow-up visits?
- Women of childbearing potential: Do you understand that if you wish to become pregnant, the tube should be removed *prior to* attempting to becoming pregnant? Contraception should be used for the duration of therapy until the A-Tube is explanted.

Patients should also be assessed for eating disorders by a qualified health professional prior to A-Tube placement. Bulimia, Binge Eating Disorder, and Night Eating Syndrome are contraindications for therapy. Typical methods for assessment in obese subjects include the Questionnaire on Weight and Eating Patterns-Revised (QEWP-R©). QEWP-R can be utilized as a screening tool and should the patient test positive on the QEWP-R, he or she should be further evaluated utilizing the Eating Disorder Examination (EDE). Patients should also continue to be monitored for development of eating disorders for the duration of treatment.

9. A-TUBE PLACEMENT

The AspireAssist A-Tube is placed using the standard ”pull” PEG technique. For the procedure, a **”pull” PEG kit is required** to place the A-Tube, as it contains the necessary supplies for the placement. The tube

from the PEG kit may be discarded. See *AspireAssist A-Tube Instructions for Use* for installation procedures.

Sedation

This procedure involves performing upper gastrointestinal endoscopy and close medical monitoring. 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.

Prophylactic Antibiotics

Antibiotics (suggested regimen: 1-2 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.

Tube Site Pain Management

Instruct patients to take over-the-counter pain medications such as acetaminophen as needed for tube site pain. In addition, at discharge from the endoscopy suite, patients should be given a 1-week prescription for pain medications that can be used to control abdominal pain or discomfort. Avoid the use of non-steroidal anti-inflammatory drugs (NSAIDS).

Instruct the patient that until the fistula has healed, there will be some discomfort, exudate, and/or small amounts of blood at the tube site. **The patient should contact the physician** if he/she experiences 1) an oral temperature of 99°F/37.2°C or above, 2) severe pain that cannot be controlled by pain medications, as this may indicate mild peritonitis; 3) excessive leakage around the tube site (gauze over the site becomes soaked), 4) if the A-Tube is dislodged or partially dislodged, or 5) or if the bolster (T-bar) is too tight against their skin.

It is important to remind the patient to minimize movement of the A-Tube to minimize pain and secretions.

It is not uncommon for patients to experience nausea, vomiting or constipation as a result of the procedure sedation, insufflated air in the abdomen, and pain medications taken in the perioperative period.

Site Management

Before discharge, assess the external bolster to determine if it is too tight against the abdominal wall when patient is in the sitting position as this can cause a pressure erosion on abdomen. Loosen the bolster as needed.

Instruct the patient to keep the A-Tube taped lightly to the abdomen and to *keep the stoma site clean and dry*. Consider using paper tape, which is less irritating than regular adhesive, to secure the gauze and tube. The bandage over the site should be replaced at least daily. If the site is noted to be wet when changing the bandage, dry with a soft clean towel and keep open to air until the site is completely dry, then apply the bandage. A thick discharge around the tube is common, particularly in the first few weeks after tube placement. This drainage is not an infection, but is the tissue reaction to the foreign A-Tube. The stoma site should be cleaned several times a day and allowed to air dry. Occlusive dressings should not be applied because these trap moisture and promote infection.

For the first 2 days after A-Tube insertion, the patient should sponge bathe but should not shower or take a bath. *After 2 days*, the patient may shower, provided that a waterproof dressing is used to cover the A-Tube and stoma site while showering. After showering, the patient must remove the dressing and use a washcloth to gently wash the site with mild unscented soap and water, and dry with a soft towel. It is important that the patient avoids manipulation of the A-Tube when cleaning the site. After cleaning, the site should be kept as dry as possible and gauze changed, as needed to ensure the site stays dry.

After one week, the patient may shower without the waterproof dressing, but bathing by submersion in water should be avoided for the first 14 days to give the fistula time to heal.

10. SKIN-PORT ATTACHMENT

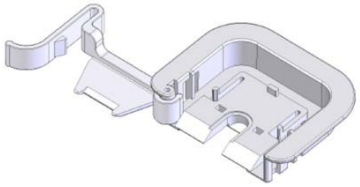
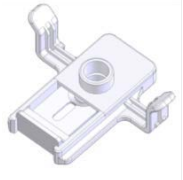
The Skin-Port is attached to the external end of the A-Tube once the stoma site is sufficiently healed, typically 7-14 days after the A-Tube is implanted. This attachment may be done earlier if the patient is experiencing discomfort due to the presence of the additional A-Tube length. Skin Port placement is generally performed in an office setting by a trained healthcare practitioner.

10.1 Skin-Port Components and Installation Tools

The Skin-Port is composed of the following components:

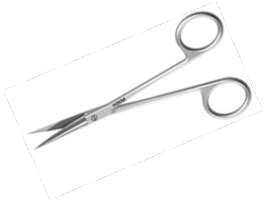
		
Valve	Sleeve	Flange

The Skin-Port Installation Tool Kit is composed of the following components:

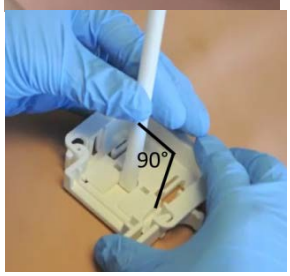
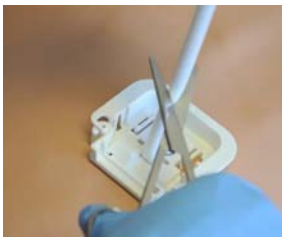
				

Clamp Tray	Tube Cutter	Sleeve Tool	Valve Opening Tool	Valve Removal Tool

Other supplies required for attachment:

		
Lint-free swabs (not included)	Standard scissors (not included)	Gauze (not included)

10.2 Skin-Port Attachment

Step 1: Clamping the Tube	
a. Wearing examination gloves, **with patient seated**, gently pull the A-Tube to ensure that the A-Tube bumper is against the stomach wall. This ensures a snug fit of the Skin-Port against the patient's skin. ***WARNING: Patient must be seated during this step, to ensure that the Skin-Port is not too tight when abdomen is compressed.*** b. Slide the existing bolster away from the skin, to make room for Skin-Port installation (do not remove yet). Gently clean the peristomal area of any exudate or other materials. c. Slide the Clamp Tray over the A-Tube (with the latch arm open), so the A-Tube rests in the center groove of the Clamp Tray, and the Clamp Tray is flush with the skin. d. Have the patient carefully lay back into a supine position, without disturbing the Clamp Tray. ✓ IMPORTANT: Check that the A-Tube emerges through the tray at approximately a 90º angle with the tray (i.e. straight up). If not, open the Clamp Tray arm and repeat Step 1. ✓ IMPORTANT: After this step, do NOT open the latch arm until Skin-Port installation is complete.	 
Step 2: Cutting the Tube a. With a pair of scissors, roughly trim the A-Tube several centimeters above the Clamp Tray. b. With the blade fully open, slide the Tube Cutter over the end of the A-Tube. Check that the arrows on the Tube Cutter and Clamp Tray are aligned. Press the Tube Cutter down into the notches in the Clamp Tray until it clicks into both sides. c. Firmly press the blade of the Tube Cutter towards the A-Tube to cut the A-Tube. d. Remove the Tube Cutter squeezing its arms together and lifting upwards.	

e. For first-time installation, a thick gastric fluid may have accumulated within the A-Tube. Use lint-free or foam swabs and gauze to remove any fluids from inside and around the visible area of the tube (above the Clamp Tray) until completely dry.
   - ✓ IMPORTANT: Do not use cotton swabs or other materials that could shed particles into the tube.

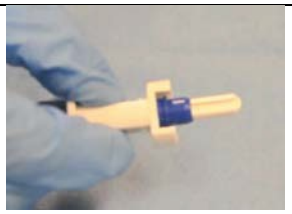
Step 3: Placing the Flange

a. Slide the Flange, with the flat side facing down, over the end of the A-Tube, and rotate it until it is fully seated in the Clamp Tray and the arrow on the Flange is aligned with the arrow on the Clamp Tray. The flange hole will be closest to the latch arm of the Clamp Tray when correctly positioned.
   - ✓ IMPORTANT: Confirm the exposed A-Tube is aligned correctly.

Step 4: Inserting the Sleeve

- ✓ IMPORTANT: Proper placement of the Sleeve into the A-Tube requires use of the Sleeve Tool.

a. Extend the pin on the Sleeve Tool fully. While holding the pin in place, slide the sleeve (sleeve head first) over the pin of the Sleeve Tool, as shown, until the head of the sleeve makes contact with the collar of the Sleeve Tool.



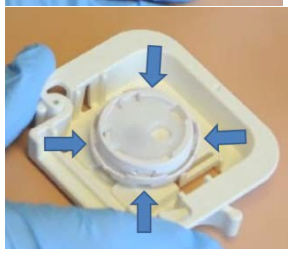
b. Lightly place the pin-end of the Sleeve tool (with the sleeve loaded) through the Flange and into the A-Tube. Hold the rim of the tray with your fingertips during this procedure to limit pressure on the patient's abdomen. Once inserted, maintain your grip on the tray rim while pressing firmly on the top of the Sleeve tool until the collar of the tool makes contact with the Flange. Once the sleeve is fully inserted so that only the head of the sleeve is visible, lift and remove the Sleeve Tool.

   - ✓ IMPORTANT: Visually inspect the sleeve to ensure that it is fully inserted in the A-Tube. If needed, use your thumbs to manually press the sleeve fully into the A-Tube.

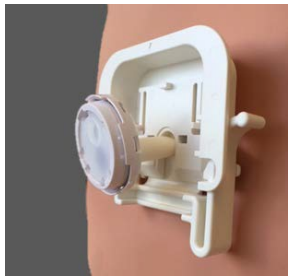
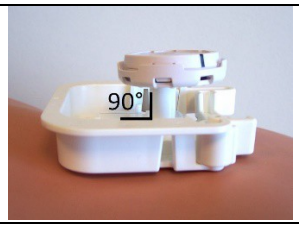
Step 5: Installing the Valve

a. If the Valve Opening Tool is not attached, insert the Valve Opening Tool into the Valve by aligning the tabs of the Valve Opening Tool into the holes of the valve (TIP: First align the largest tab in the tool with the largest hole in the valve). Once fully inserted, hold the valve and turn the Valve Opening Tool clockwise fully so the thru-hole in the valve is open.

b. Place the Valve / Valve Opening Tool gently on the Flange, so that the larger "fin" on the Valve Opening Tool points towards the arrow on the clamp tray. Look closely to check that the four feet at the bottom of the Valve are aligned with the holes in the Flange.

c. Using both hands, slide your fingertips under the rim of the Tray on each side of the latch arm. Using your thumbs, press firmly on the center of the valve, then around the edges of the valve. Listen carefully for all four clicks during this step. d. While applying downward pressure, turn the Valve Opening Tool counter-clockwise to close the valve, and lift the Valve Opening Tool to remove. ✓ IMPORTANT: Visually inspect that all four feet of the valve are engaged securely into the Flange. The feet should be visible in the four of the holes in the Flange. If any of the four feet are not engaged correctly in the Flange, ensure correct alignment of the Flange and Valve, then press on the corners of the Valve Opening Tool, until the remaining feet snap into place.	 
Step 6: Remove Clamp Tray a. Open the latch arm on the Clamp Tray and remove the Clamp Tray. Note that the Skin-Port will sit approximately 1 cm from the skin due to the thickness of the clamp tray (6 mm) and the patient's positioning. Once again, gently clean the peristomal area of any exudate or other materials. The Skin-Port installation is complete.	

10.3 A-Tube Shortening

Step 1: Clamping the Tube a. Wearing examination gloves, gently clean the peristomal area of any exudate or other materials. **b. With patient seated**, latch the Clamp Tray over the A-Tube, between the Skin-Port and the Skin, so that the tray is flush with the skin. The A-Tube should emerge from the tray at approximately a 90º angle**.** ***WARNING: Patient must be seated during this step, to ensure that the Skin-Port is not too tight when abdomen is compressed.*** ***WARNING: Do not shorten the A-Tube unless the Skin Port extends above rim of the tray.*** c. Have the patient carefully lay back into a supine position, without disturbing the Clamp Tray.	
✓ IMPORTANT: Check that the A-Tube emerges through the tray at approximately a 90º angle with the tray. If not, open the Clamp Tray arm and repeat Step 1.	

Step 2: Remove the Skin-Port a. Place the Valve Removal Tool on top of the Skin-Port, aligning the four legs on the Valve Removal Tool with the four feet on the Valve. b. Press the Valve Removal Tool and the Skin-Port together until the Valve disengages from the Flange. Lift the Valve (with Valve Removal Tool) out of the Flange. c. Remove the Sleeve from the Flange and A-Tube manually. If the Sleeve cannot be easily removed by hand, a pair of forceps or other grasping instruments may be used. d. Remove the Flange from the A-Tube, discard the Skin Port Valve, Flange and Sleeve and obtain a new Skin Port.	
Step 3: Attach the new Skin-Port a. To shorten the A-Tube and attach the new Skin-Port, follow instructions in **Section 10.2 Skin-Port Attachment**, beginning with Step 2.	

10.4 If the Skin-Port Detaches Unexpectedly

In the case of accidental Skin-Port detachment, the Emergency Clamp should be retained on the A-Tube until Clamp Tray is latched to prevent leakage of stomach contents and migration of the A-Tube. Follow the instructions in **Section 10.3 A-Tube Shortening** to place the Clamp Tray, remove the old Skin Port if necessary and attach the new Skin Port.

11. ASPIREASSIST COMPANION SETUP AND TRAINING

Approximately two weeks after the A-Tube is placed, once the stoma tract has healed, the patient should be trained on using the device, and perform the first aspiration in the clinician's offices.

11.1 AspireAssist Training Meal and Principles of Therapy

Provide the patient with a small meal that is easy to aspirate, such as yogurt, cereal, granola bars, or applesauce and fluids to assist with aspiration. The patient should be counseled to chew this meal very carefully to facilitate this aspiration.

The clinician should review the principles of AspireAssist therapy with the patient:

☐	The AspireAssist is a **useful tool** to help with weight loss, but **healthy eating behavior** is the key to long-term weight management. Over time, the most successful patients reduce their calorie intake, eat healthier foods, and continue aspirating regularly.

☐	**You must chew all foods completely.** Remember that everything you eat needs to fit through the holes in the tube (6mm diameter, about the size of a pencil eraser). If you're getting frequent clogs, you're probably not chewing enough.
☐	Aspiration should be performed about **20 to 30 minutes after each major meal** (about 3 times per day), to give food time to break into smaller pieces in the stomach. Some foods may require more time to digest. Aspirating later is still better than not at all.
☐	**Snacking should be minimized** since snacks are not aspirated. This includes high-calorie drinks, such as soda, juice, and alcohol.
☐	Drink plenty of water to facilitate aspiration, prevent dehydration, and assist with weight loss
☐	Bring your Carry Bag with you everywhere, and make sure the emergency clamp is in it at all times.
☐	Complete the Aspiration Journal daily, and bring it with you to check-ups.
☐	Aspiration removes about 25%-30% of the calories after a meal, when performed properly.

11.2 AspireAssist Companion and Accessories Setup

Before the first aspiration, the external components must be customized to the appropriate length for the patient using the following instructions.

Step 1: Trim the Lanyard	
a. Attach the empty Reservoir, Tubing Set, and Lanyard to the Companion, then attach the Connector to the Tubing Set. See Patient Guide for details. Hang lanyard around patient's neck. b. Determine a comfortable height for the Companion. The patient should be able to comfortably squeeze the reservoir and hold the Companion. The Companion must be **below the level of the stomach** for the device to work properly, as it operates using gravity. Generally it is better to leave the lanyard and tubes longer initially, and shorten again if necessary. c. Mark the amount of length to remove on the lanyard, and remove from patient's neck. Open the metal tab on the lanyard, cut with scissors, and re-insert the lanyard into the metal tab and close the tab.	
Step 2: Trim the Connector Tube a. With lanyard trimmed appropriately, hang the system around the patient's neck again. Allow the lanyard to support the system fully. b. Determine the appropriate length of the Connector Tube to allow the Connector to easy reach the Skin-Port. If shortening is required, remove the Connector, cut the top of the Connector Tube with scissors, and reattach the Connector.	
Step 3: Trim the Drain Tube **a.** With patient standing next to a toilet and the system hanging around neck, determine the appropriate length for the drain tube. It should hang over seat of the toilet to guide stomach contents into toilet, **but must not touch the water.** b. Because the height of toilets vary, it is generally better to leave some extra length until the patient has determined the optimal length to accommodate the toilets at home, work, etc. c. Use scissors to trim the drain tube. Discard all removed tubing and lanyard.	

11.3 AspireAssist Operation Training

Approximately 20 to 30 minutes after the meal has been ingested, the patient should connect the AspireAssist themselves and aspirate their training meal in the clinican's office (typically in a private restroom, if available). Refer to *Patient Guide* for complete instructions. They should understand or demonstrate the following skills before leaving the office:

☐	**Assembly:** Ensure patient can assemble the components of the AspireAssist, and connect to Skin-Port. Helpful hints: - Ensure drain clamp is closed until patient is ready to aspirate (standing over toilet). - Small bump on the Skin-Port shows where to initially line up the connector lever (then turn Connector clockwise until it "drops" into place). - Connector lever must be fully turned to open the value (almost ¼ turn past the "click"). - Fill reservoir, leaving a small amount of air in the neck. Use warm water (but not hot). Warm water is most comfortable and effective.
☐	**Operation:** - Check that patient can close the clamp to infuse water, and open the clamp to begin draining - Patient should try squeezing abdominal muscles, coughing, changing position (but always stay standing), infusing more water from the Reservoir, or pinching the Connector Tube to start flow - Aspiration is complete when there is fluid draining with no visible food and stomach feels empty - Connector can connect 115 times before it becomes disabled. Additional Connectors must be obtained from physician to continue therapy after 115 uses.
☐	**Cleaning:** - <u>After each aspiration</u>, rinse the system in the sink. - <u>Once per day</u>, rinse system with water and mild dish soap, then rinse thoroughly with clean water. Do not soak in alcohol. - <u>Once per week</u>, soak system (except Connector) overnight in equal parts water and distilled white vinegar, or water and baking soda. **Do not place in dishwasher or microwave**.
☐	**Stoma Site Care:** - Wash site with warm clean water and mild soap daily and always keep dry (except while washing). - Gauze pads can be placed under Skin-Port. Change regularly to keep stoma site dry.
☐	**Medication:** - Determine appropriate times to take medications to ensure that they are not aspirated. All medications should be taken at least 2 hours before aspirating. Immediately after aspirating is often a good time. Medications may also be taken at bedtime as this will not conflict with aspiration.
☐	**Clogging** - If the A-Tube cannot be cleared by warm water infusion, wait several hours, then try again. If the tube remains clogged after 24 hours, contact your physician or nurse to have the A-Tube unclogged. Never infuse hot water into stomach.

☐	**Review all warnings and cautions** in *Patient Guide* with patient.

11.4 Dietary Recommendations for First Two Weeks

As patients are initially learning to aspirate, it is recommended that they begin with a diet that requires minimal chewing. This enables the patient to experience successful aspirations without clogging while they are initially learning to use the device. This reduces the early frustrations patients experience before they learn to chew their food successfully. It also allows them to recognize later when they haven't chewed their food properly because the food begins to clog more than in the initial weeks.

Stage 1: Pureed Foods

For approximately one week, patients are encouraged to eat only foods that require no chewing. This includes mashed or pureed foods that have a smooth consistency. They can use a food processor or blender to get foods to this consistency. With these foods, meals should aspirate very easily.

Stage 1 Food Examples		
Fruits and Vegetables	Grains and Carbohydrates	Protein
Smoothies	Mashed potatoes (smooth)	Finely minced meats (i.e., with food processor)
Smooth soups (not chunky)	Oatmeal	Cottage cheese
Pureed vegetables or fruits, such as applesauce	Rice	Yogurt

Stage 2: Soft and Ground Foods

For the second week, patients can begin eating foods that *require minimal chewing,* similar to a mechanical soft diet. This includes very well cooked vegetables, fruit that is chopped to 6mm diameter (the size of a pencil eraser) or smaller, finely ground meats, and soft fish. With these foods, meals should still aspirate very easily. If aspirating is more difficult now and clogging begins, they will need to chew their food more carefully and choose foods that require less chewing.

Stage 2 Food Suggestions		
Fruits and Vegetables	Grains and Carbohydrates	Protein
Well-cooked or very finely chopped vegetables	Cereal	Ground Meats, including meatloaf or meatballs
Soft fruits such as banana, watermelon, pears, raspberries	Soft bread, cut into small pieces	Eggs (scrambled)
Finely chopped fruits	Well-cooked pasta	Soft fish (boiled, baked or broiled)
Canned fruits	Casseroles with ground meats and finely chopped vegetables	Tuna, Egg, or Chicken Salad (without celery)

Stage 3: All foods

The beginning of Stage 3 typically coincides with a follow-up visit. If the patient can aspirate easily with Stage 2 Foods, more difficult foods can slowly be introduced into the diet. The goal is for aspiration to be just as smooth as during Stage 1 and 2. There may still be some foods that do not aspirate easily, even with thorough chewing. In this situation, the patient should continue to cut these foods into very small pieces and try waiting up to an hour after eating to aspirate it. If these still cause clogging, the patient may need to avoid that food until he or she has become more proficient with chewing. Remind patient to drink plenty of fluids such as water or low calorie beverages.

11.5 Maintenence Use of the AspireAssist

As the patient begins to approach his or her target weight, the patient may be able to reduce the frequency of aspirations if sufficient lifestyle changes have been made. In this case, the patient should reduce the frequency of aspiration to two times per day, and monitor weight to ensure that he or she can maintain the weight loss at this frequency. Eventually, the patient may be able to aspirate once per day or less and still maintain his or her weight loss. If a patient desires to have the device removed, it is recommended that patients take at least a 3-month "holiday" from using the device, before it is removed, and monitor their weight during this time. Many patients will require long-term therapy with the device to maintain their weight loss.

12. ROUTINE FOLLOW-UP VISITS

Patients must be closely monitored while they are using the AspireAssist, and must return for all follow-up visits. The following should be monitored on a regular basis (please review **Suggested Visit Schedule** below for the recommended follow-up visit schedule based on clinical experience.)

12.1 Elements of Follow-Up Visits

Weight Loss

- Review weight loss objectives and progress with patient. Target weight loss using the AspireAssist is 1 to 2 pounds (0.5-1 kg) per week. Set small, achievable goals.
- If weight loss is too rapid or too slow, see **Troubleshooting**.

Aspiration Progress and Adherence

- Review ease of aspiration, time to aspirate, and adherence to aspiration schedule. If any difficulties are identified, see **Troubleshooting**.
- Record the number of aspirations remaining on the Connector and calculate the number of aspirations per day since the last visit, to determine if patient is aspirating appropriately (3 times per day). Provide a new Connector if necessary.
- It is recommended that all patients take a multivitamin and mineral supplement daily for the duration of therapy. Confirm adherence to recommended regimen.

- Ensure patient is taking any prescribed medication or supplements immediately after aspirating, or at least 2 hours before the next aspiration to ensure full dosage is absorbed.
- If patient has lost significant weight, dosage of some medications may need to be adjusted.

Stoma Site Health

- Check for infection, exudate, or granulation tissue. If treatment is required, see **Management of Selected Medical Complications** for suggested care.

A-Tube Length Check

- Check Skin-Port distance from skin with patient in sitting position. The Skin-Port must not be so tight that it exerts tension on the internal A-Tube bumper. Excessive tension could cause the bumper to migrate into the fistula, and A-Tube replacement may be necessary.
- If necessary, shorten the A-Tube. See **Section 10.3 A-Tube Shortening.**

Eating Disorder Surveillance

- At each regular visit, the clinician should monitor the patient for signs of eating disorders. The following may suggest development of dysfunctional eating behaviors: 1) Aspirating more than three times per day, or 2) Lack of weight loss despite frequent aspiration. **See 15.3 Eating Disorders**.
- Assessment tools such as the QEWP-R may be used periodically to detect eating disorders for the duration of therapy. Assessments should be administered by a trained healthcare professional.

Bloodwork

The following serum laboratory values should be checked regularly, particularly potassium. Aspiration of stomach fluids could cause hypokalemia, primarily due to renal potassium excretion. *Monitoring blood potassium concentration regularly is critical for medical safety of the patient particularly in patients who are prescribed diuretic therapy.* If treatment is required, see **Management of Selected Medical Complications** for suggested care.

- Electrolyte Panel: Sodium, Potassium, Chloride, CO_2 (quarterly). Some patients, particularly those taking diuretics, may require additional electrolyte monitoring at the physician's discretion.
- Complete Blood Count (CBC): hemoglobin, hematocrit, red blood cell count, white blood cell count and differential, mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), platelet count (semi-annually and as deemed necessary based on medical history)
- Complete Metabolic Panel (CMP): glucose, calcium, sodium, potassium, chloride, CO_2, BUN, creatinine, albumin, alkaline phosphatase, ALT, AST, and bilirubin (semi-annually and as deemed necessary based on medical history)

Lifestyle Counseling

Lifestyle counseling must be provided with the AspireAssist by a trained healthcare professional (e.g., dietitian) during routine visits, or separately. See Section 13.1.

12.2 Recommended Follow-up Visit Schedule

The following is a suggested visit schedule for AspireAssist patients. Some patients may require additional monitoring based on their individual health and progress. In addition, monthly lifestyle counseling sessions should be provided to reinforce healthy dietary and exercise behaviors. These lifestyle sessions should include a weight measurement, connector count check, aspiration progress, and stoma site health to determine the need for additional medical visits.

Week	Visit Type	General Progress						Bloodwork	
		Weight	Aspiration Progress	Stoma Site Health	A-Tube Length Check	Eating Disorder Assessment	Medication Use**	CBC/ CMP*	Electrolyte Panel
	First Year								
Week 0	A-Tube Placement (Endoscopy)	X					X		
Day 1	Check-Up Phone Call			X					
Week 1	Skin-Port Conversion (Office)			X					
Week 2	AspireAssist Training & Begin Therapy (Office)	X		X	X		X		
Week 2.5	Check-Up Phone Call		X						
Week 4	Office Visit	X	X	X	X		X		
Week 8	Office Visit	X	X	X	X		X		
Week 12	Office Visit	X	X	X	X		X		X
Week 26	Office Visit	X	X	X	X	X	X	X	
Week 38	Office Visit	X	X	X	X		X		X
Week 52	Office Visit	X	X	X	X	X	X	X	
	Quarterly Visits After Year 1								
Q1	Office Visit	X	X	X	X		X		X
Q2	Office Visit	X	X	X	X	X	X	X	
Q3	Office Visit	X	X	X	X		X		X
Q4	Office Visit	X	X	X	X	X	X	X	

**Complete Blood Count (CBC) / Complete Metabolic Panel (CMP) should include Electrolyte Panel*
***diabetes, hyperlipidemia and hypertension*

13. LIFESTYLE COUNSELING AND OTHER SUPPORT PROGRAMS

13.1 Lifestyle Modification Program

The most successul AspireAssist patients make substantial changes to their diet and exercise routines. With substantial changes, patients may be able to reduce the number of aspirations per day, or even discontinue treatment completely, without regaining weight. Patients should receive lifestyle counseling sessions with a trained healthcare professional (e.g., dietitian) monthly thoughout the first year and on a quarterly basis thereafter. It is recommended that patients *initially focus on using the device and chewing properly*, until they have mastered the device. Once the patient is proficient with aspiration, they can

gradually make changes to their eating habits and begin incorporating physical activity. Small achievable goals are suggested for best results.

In addition, these lifestyle sessions should include a weight measurement to detect excessive or inadequate rate of weight loss, connector count check, discussion of aspiration flow and adherence, and stoma site health to determine the need for additional medical visits with a physician or nurse.

13.2 Group Sessions

Group sessions, held on a monthly or quarterly basis, are highly recommended. Such sessions allow patients to provide and receive support, share experiences and suggestions with using the device, and motivate each other. These sessions are typically organized by the medical team, and can also be used to provide lifestyle counseling or medical check-ups.

13.3 Patient Mentors

Patient mentorship is another optional program that can be organized by the medical team. With such a program, new AspireAssist patients are paired with experienced AspireAssist patients to communicate independently.

13.4 Online Resources

Patients can visit aspirebariatrics.com for information on confidential online support communities and other resources.

14. DEVICE TROUBLESHOOTING

14.1 Skin-Port Troubleshooting

The Skin-Port Feels Loose

As patients lose weight, the tube will protrude farther from the abdominal wall; the patient should have the A-Tube shortened at the next regular check-up. Always assess with patient in the sitting position.

The Skin-Port Feels Tight

If the Skin-Port feels tight due to weight gain or improper Skin-Port attachment, patients should return to the doctor's office immediately. The tube may need to be replaced to prevent complications such as a buried bumper.

The Skin-Port Becomes Disconnected

The patient should attach the emergency clamp onto tube immediately to prevent migration of A Tube into stomach. A trained medical professional should attach a new Skin-Port as soon as possible. See **Section 10.4**.

14.2 A-Tube Troubleshooting

The Tube Becomes Clogged

If the patient's tube has been clogged for 24 hours or more, it may need to be manually cleared in the clinician's office using an endoscopy brush. First, mark the brush to a length corresponding to the distance between the external end of the A-Tube and the bumper, plus 4.5 cm to account for the distance between the bumper and the first aspiration hole. Attach the Value Opening Tool to the Skin-Port to open the valve. Gently insert the brush through the Valve Opening Tool and Skin-Port and into the A-Tube, avoiding excessive force, to dislodge the clogged substance. Do not insert the brush beyond the mark and hence beyond the first aspiration hole. Be sure to hold the A-Tube to prevent the tube from falling into the fistula in the event that the Skin-Port disconnects during this process. Afterwards, the patient should attempt to aspirate. If manual clearing is unsuccessful, an endoscopy may be necessary, and the tube might need to be replaced. At the time of endoscopy, try to unclog the tube by passage of an endoscopy brush under direct endoscopic visualization. If the obstruction cannot be removed, the tube must be replaced.

The Tube Becomes Darkened or Discolored.

Darkening and discoloration occur normally with use, and is not a concern unless the tube becomes brittle, cracked, or has expanded. A short segment of expansion may be a sign of microbial ingrowth into that segment of the tube. Although the A-Tube typically lasts more than one year, and often much longer, it should be replaced if there are any signs of deterioration.

14.3 Aspiration and Weight Loss Troubleshooting

Aspiration is Difficult.

The most common cause for aspiration difficulties is failure to chew thoroughly. Patients frequently underestimate the degree of chewing that is required. To evaluate patient's chewing technique, the patient should aspirate a meal in the clinician's office under observation by a trained clinician and/or a patient mentor, if patient agrees (See **Section 13.3 Patient Mentors**). Note that patient should not eat within 2 hours of the visit, to ensure stomach is empty (fluids are acceptable). To begin, patient should consume a fully soft meal, such as applesauce, yogurt, or smoothie with at least 16 ounces (500 mL) of water. While aspirating, confirm that patient is familiar with various techniques such as body repositioning and squeezing the Connector Tube (see *Patient Guide*).

If food empties easily with soft foods, the patient should be counseled on the importance of chewing, drinking water, and waiting 20 or more minutes to aspirate. Discuss with patient their typical schedule and technique, to determine where the additional training is necessary. At this point, consider asking the patient to consume a typical meal and demonstrate aspiration with this meal to troubleshoot. Additionally, consider having patient return to Stage 1 or 2 foods for several days to re-learn what a successful aspiration should look like, then gradually returning to a normal diet.

If aspiration is difficult with soft foods, there may be a clog in the A-Tube or the A-Tube may have rotated or kinked within the stomach. Attempt to clear the tube manually with an endoscopy brush (see **Section 14.2 A-Tube Troubleshooting).** If unsuccessful, x-ray imaging can be used to determine if the A-Tube is

improperly positioned in the stomach. The A-Tube is radiopaque and will be visible with x-ray. If the A-Tube is kinked or has rotated towards the pylorus, the tube can be repositioned using the endoscope and a snare during an endoscopy, or replaced if repositioning is unsuccessful. Repositioning the A-Tube should only be performed if the tube is less than 6 months old and if, on inspection during endoscopy, there are no visible deformities such as a bulge in the tube. If the A-Tube has been in place for more than six months or if there is any visible deformity it is recommended that it be replaced.

Patient is not losing weight.

The most common causes for this situation are:

1. Patient is not aspirating 3 times per day. Counsel patient on importance of aspirating regularly and help troubleshoot barriers, such as difficulty aspirating at work.

2. Aspiration is inefficient. Typically this is due to poor chewing, so less than 25%-30% of the calories are being removed. See above, **"Aspiration is Difficult",** for guidance on an in-office aspiration evaluation.

3. Snacking or drinking. Patient is consuming large portion of calories outside of main meals, such as alcoholic or other high-calorie beverages, or frequent snacking. Review food journal and counsel patient. If the patients schedule or lifestyle causes meals to be eaten in an unconventional manner, then suggest aspirating the 3 largest "meals" per day. In this case, lifestyle counseling should work to address these behaviors gradually.

In rare cases, lack of weight loss despite frequent aspiration may be a sign that the patient has developed dysfunctional eating behaviors. See **Section 15.3 Eating Disorders**.

Patient experiences excessive weight loss, or excessive rate of weight loss.

If the patient is losing weight too rapidly, the patient should decrease the frequency of aspiration and the issuance of new Connectors should be delayed until weight loss returns to a healthy rate. Closely monitor number of aspiration counts at each visit. If the patient experiences excessive weight loss, AspireAssist therapy should be reduced or discontinued until the patient returns to a healthy weight. The patient should be evaluated for dysfunctional eating behaviors. See **Section 15.3 Eating Disorders**.

15. MANAGEMENT OF SELECTED MEDICAL COMPLICATIONS

15.1 Stoma Management

Granulation tissue

It is normal for granulation tissue to form at the ostomy site of the A-Tube. This granulation tissue is friable and often bleeds when touched. If the granulation tissue is excessive, causing discomfort or significant bleeding, the following treatments may be helpful:

- **Silver nitrate sticks**: Gentle contact of the granulation tissue with the tip of the silver nitrate stick will reduce or completely remove the granulation tissue. The area should be swabbed with alcohol before

and after treatment. Care should be taken to ensure that silver nitrate does not come into direct contact with normal skin tissue or A-Tube.

- **OTC skin protectant/external analgesic/anti-itch/tissue astringent:** Use according to the manufacturer's instructions. Care should be taken to only apply product to granulation tissue and avoid contact with irritated skin.

Peristomal rash, skin irritation, or erythema

These complaints can be treated with zinc oxide or other skin barrier products (such as Desitin® cream, or Stomahesive® powder). Make sure the Skin-Port is not tight when the patient is in a seated position. In addition, a dry keyhole gauze dressing placed under the Skin-Port can provide some relief. If there is no evidence of fungal infection, over-the-counter hydrocortisone cream (0.5%) can be used. Remind patient to keep the peristomal skin as clean and dry as possible.

Peristomal discharge

A thick discharge around the tube is common, particularly in the first few weeks after tube placement. This drainage is not an infection, but is the tissue reaction to the foreign A-Tube. The ostomy site should be cleaned several times per day with a mild soap and allowed to air dry. Occlusive dressings should not be applied because these trap moisture and promote infection.

Peristomal infection

Local infections at the A-Tube site can usually be treated with oral medication for bacterial infection (e.g. cefadroxil, cephalexin) or topical cream for fungal infection (e.g. nystatin), as needed. If there is considerable purulent drainage, obtaining a culture of the discharge should be considered to help guide the choice of antibiotic.

Subcutaneous abscess

Small areas of redness or fluctuance around the tube may indicate a peritubal subcutaneous abscess. This can be treated with appropriate antibiotics (e.g., cefalexin) or by making a small incision into the abscess under local anesthesia and irrigating the site with hydrogen peroxide.

Peristomal leakage

Leakage can be caused by (i) failure of the stomach stoma to heal around the tube, (ii) enlargement of the stomach stoma (sometimes caused by an infection within the tract or mechanical forces from excessive tube manipulation), or (iii) buried bumper syndrome. The tube should be checked to make sure it can move freely in and out within the fistula tract to rule out the possibility of a buried bumper. If there is no evidence of a buried bumper, the patient should be instructed (i) not to aspirate and (ii) to avoid any manipulation around the tube to allow the stomach stoma to heal and form a tight seal. If skin irritation or excoriation occurs, skin care recommended for peristomal irritation can be started. A short-term (2 week) treatment with Proton Pump Inhibitors (PPIs) may also be considered to reduce peristomal irritation due to stomach acid. If leakage persists after several days, the A-Tube can be removed temporarily and replaced with a smaller diameter gastrostomy tube and the tract allowed to partially

close. A new A-Tube can then be placed through the same site. Monitor the stoma tract closely while the A-Tube is removed.

Persistent fistula after A-Tube removal

Although fistulas typically close within a few days after A-Tube removal, some patients will require additional treatment if the fistula does not heal spontaneously within 4-6 weeks after A-Tube extraction. See **Section 18: A-Tube Removal and Replacement.**

15.2 Electrolytes and Metabolic Health

Hypokalemia

A decrease in serum potassium (K) concentration can occur with repeated aspiration of gastric contents because of the loss of gastric acid and compensatory potassium excretion by the kidney. This may be exacerbated by patients who are taking medications that affect serum potassium such as a diuretic. If serum potassium decreases to a clinically significant level, review medical history to identify possible causes for hypokalemia. Potassium supplementation should be initiated or increased and serum K+ checked after 2 weeks, and other medications adjusted accordingly if necessary. Use of the AspireAssist can continue while additional potassium therapy is being given if the cause is not related to the AspireAssist and the decrease in potassium is not severe.

Iron deficiency anemia

Iron deficiency anemia can occur in AspireAssist patients due to weight loss, including increase or restoration of menses following weight loss, obesity itself, or because of decreased iron absorption due to aspiration. Iron rich foods should be recommended. If required, iron supplementation should be considered. If a patient experiences a significant decrease in serum hemoglobin (>1g/dL), additional iron supplementation with a readily absorbed iron formula can be used.

Dehydration

Patients should be encouraged to drink water throughout the day, plus at least 500mL of water with each meal, to prevent dehydration. Volume depletion can be treated with low-calorie sodium-containing foods (e.g. pickles or bouillon cubes) that are consumed without aspiration, in conjunction with increased water intake. Severe dehydration may require intravenous therapy.

Abdominal pain

Musculoskeletal or neuropathic complaints (e.g. burning, pulling, stinging, radiating pain, muscle spasm, or intermittent sharp pain) after tube placement are usually effectively treated with general oral pain medications and/or medications for neuropathic pain (e.g. gabapentin).

15.3 Eating Disorders

In the US Clinical Study, one patient in the Control group (1.7%) and one patient in the AspireAssist group (0.9%) developed a suspected eating disorder. If dysfunctional eating behavior is suspected, the patient should be evaluated by a trained healthcare professional. If a positive diagnosis is made, or an eating disorder is strongly suspected, use of the device should be discontinued and the patient should undergo psychological counseling to treat the disorder. The physician may also consider A-Tube removal.

16. SPECIAL POPULATIONS

16.1 Diabetes

Note: All patients with diabetes should continue to visit their diabetologist regularly for diabetes care after beginning AspireAssist therapy.

Warning: The safety and effectiveness of the AspireAssist has not been established on patients with HbA1c >9.5% or patients treated with insulin or sulfonylureas.

Diabetes medications (biguanides, thiazolidinediones, GLP-1 agonists and/or DPP-IV inhibitors) do not require changing immediately after starting AspireAssist therapy because the continued use of these medications should not result in an increased risk of hypoglycemia. However, the use of these medications may decrease and possibly be discontinued completely as patients absorb fewer carbohydrate calories and lose weight with treatment.

Patients should check (by fingerstick) a fasting glucose every morning after starting AspireAssist therapy. Patients should be instructed to contact their physician immediately if their fasting blood glucose is <70 md/dL or >200 mg/dL. Any changes in diabetes medications should be made in conjunction with any other physicians managing the patient's diabetes, to ensure medical care iscoordinated.

If the A-Tube is explanted, patients with diabetes who have lost weight and have had a reduction in their diabetes medications will need additional blood glucose monitoring. Adjustments in diabetes medications may be necessary to maintain adequate glycemic control.

16.2 Patients with Osteopenia, Osteoporosis or Over Age 65

Patients with diagnosed osteoporosis or osteopenia and patients over age 65 may be more susceptible to decreases in bone mineral density with weight loss. Monitoring for reduction in bone mineral density through bi-annual DEXA scanning is recommended for this population. These patients may benefit from additional calcium supplementation and increased physical activity such as a regular weight bearing exercise program.

16.3 Pregnancy

The AspireAssist has not been studied in pregnant women. Female patients with childbearing potential should be counseled to use contraceptive methods while the A-Tube is implanted. If a patient wishes to become pregnant, the A-Tube must be removed prior to attempting to conceive.

If a patient becomes pregnant at any time while the A-Tube is implanted, the A-Tube should be removed before the Skin-Port becomes tight due to weight gain or abdominal expansion. The patient's obstetrician should be consulted to determine the optimal timing for this procedure, to minimize risk to the patient and fetus.

17. MAGNETIC RESONANCE IMAGING

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.

18. A-TUBE REMOVAL AND REPLACEMENT

The A-Tube must be removed endoscopically, utilizing a snare to pull the tube out through the mouth. See *A-Tube Instructions for Use* for removal and replacement instructions. A PEG "pull" kit is required for replacement of the A-Tube.

If the A-Tube is to be removed and has been in place for more than 12 months, during removal the 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 or heavy lifting during the healing process, and always maintain good skin care practices at the stoma site.

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.

19. ACCESSORIES REPLACEMENT

The AspireAssist Companion and all accessories are intended to be consumable products, and should be replaced periodically. The products may have reached the end of their useful life if they fail to operate as intended, or have accumulated an excessive odor, discoloration, or build-up of foreign matter that cannot be removed using the recommended cleaning methods described in the Patient Guide.

19.1 Connector

The Connector must be replaced after 115 cycles. The counter digit will be displayed in red beginning with 19 cycles left, indicating that the Connector will need to be replaced soon. When the Counter reads "00", the patient has completed 115 cycles and a new Connector must be obtained through the clinician. If the patient tries to continue to use the Connector, it will then read "- 9" and lock up to prevent future use. To replace the Connector, detach the old Connector from the Connector Tube, and attach the new Connector to the tube. It is important to have the patient bring the Connector to all follow-up visits.

19.2 Tubing Set and Reservoir

The Tubing Set, which includes a Connector Tube, Drain Tube, and T-Fitting, may be replaced as desired, due to odor or discoloration that cannot be removed using the cleaning methods described in the Patient

Guide. On average, the tubing sets need to be replaced approximately every 6 months, and the Reservoir needs to be replaced approximately every 3 months, however this will vary by the frequency of use and care given to each item. Remind the patient not to overfill the reservoir and to be gentle when infusing water into the stomach. They should squeeze slow and steady and infuse about a quarter to a third of the bottle each time. Each new Drain Tube and Connector Tube should be cut to the appropriate length by the clinician before use.

19.3 Companion

The Companion is designed to last for 12 months. This may vary with frequency of use and care given to the Companion.

19.4 Skin Port

The Skin Port is designed to last for up to 6 months.

19.5 A-Tube

The A-Tube is manufactured from medical grade silicone and designed to withstand the acidity of the stomach as well as the temperature of the body. The majority of patients will have the same A-Tube for one year or more. However, 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.

It is very important to inspect the section of the A-Tube between the abdomen and the Skin Port. Look for any discoloration, black spots or swelling. The A-Tube may start to break down as a result of biofilms which are naturally occurring in the digestive system. The A-Tube would then need to be replaced through an endoscopic procedure similar to the original placement. However, since the replacement tube is placed in the same stoma site, there is very little if any discomfort in this area.

20. LIMITED WARRANTY

The AspireAssist and its components are warranted against manufacturing defects only. Since these products are consumables, this warranty does not cover damage attributable to or resulting from normal wear (including odors, discoloration, build-up of foreign matter) or abuse of the products. This warranty also does not cover alteration of the product or use of the product contrary to the Patient Guide.

For patients in the United States, warranty claims must be made through Aspire Bariatrics directly. For patients outside the United States, warranty claims must be made through the authorized AspireAssist distributor in that country. This warranty is limited to the replacement of the defective part. Aspire Bariatrics shall in no event be responsible for any incidental or consequential damages other than as expressly provided by specific law.

This limited warranty is the only express or implied warranty applicable to the Aspire products. Any implied warranties, including warranties of merchantability and fitness for a particular purpose shall be limited in scope and duration in accordance with this limited warranty.

21. SYMBOLS

	Catalog number		Batch code
	Manufacturer		Use by date
	Consult instructions for use		Authorized representative in the European community
	MR Safe		

22. CONTACT

Aspire Bariatrics, Inc.
319 N Pottstown Pike, Suite 202
Exton, PA 19341 USA

www.aspirebariatrics.com
info@aspirebariatrics.com

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