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User's Manual

**CAUTION-Investigational Device.
Limited by Federal Law
to Investigational Use.**

Aspire Bariatrics, Inc.
3200 Horizon Drive, Suite 100
King of Prussia, PA 19406 USA
United States of America

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1 – Introduction

1.1 INTENDED USE

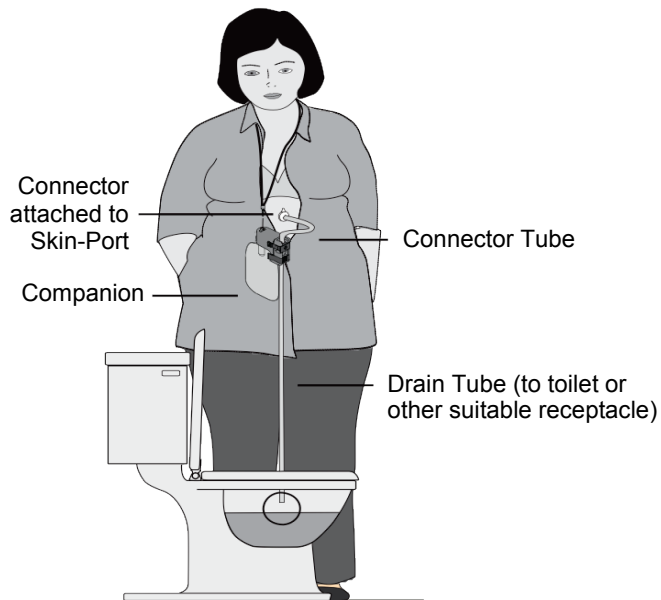
The AspireAssist® Aspiration Therapy System is intended to assist in weight reduction of obese patients. It is indicated for use in adult patients with a Body Mass Index (BMI) of 35.0-55.0 kg/m² who have failed to achieve and maintain weight loss with non-surgical weight loss therapy. The AspireAssist is to be used in conjunction with lifestyle therapy and continuous medical monitoring. The AspireAssist is intended for a **long-term** duration of use, which requires continual medical monitoring.

1.2 DEVICE DESCRIPTION

1.2.1 System Overview

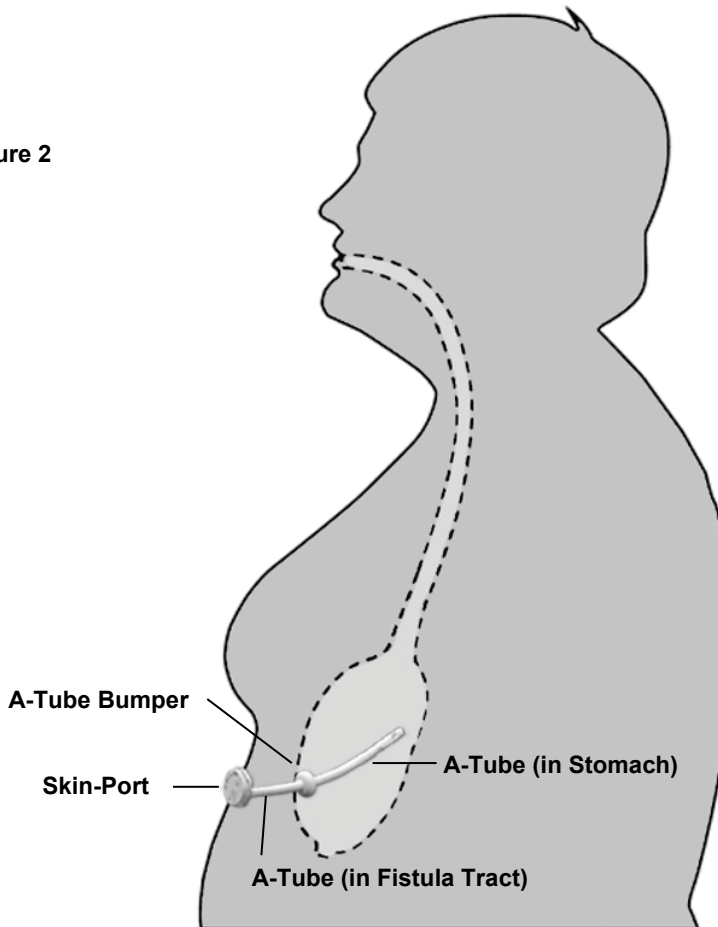
The **AspireAssist** consists of three parts:

1. **A-Tube™** - a tube that is inserted through the belly and into the stomach in an endoscopic (video camera in a tube inserted down the esophagus and into the stomach) medical procedure. The A-Tube connects the inside of the stomach to the outside of the abdomen.
2. **Skin-Port™** - a disc that sits slightly less than 1 cm above the skin, attaches to the end of the A-Tube on the outside of the abdomen, and controls the opening and closing of the A-Tube
3. **Companion™** - a hand-held device that connects to the Skin-Port, helps stomach contents flow more easily out of the stomach through the A-Tube, and empties into a toilet. The food emptying process is called Aspiration Therapy.



1.2.2 A-Tube

Figure 2



Skin-Port

Controlled entryway to the A-Tube that attaches to the Connector and keeps the A-Tube in place.

Stoma / Tract

The stoma is the opening in the belly. The tract is a channel created between the skin and the stomach that surrounds the A-Tube.

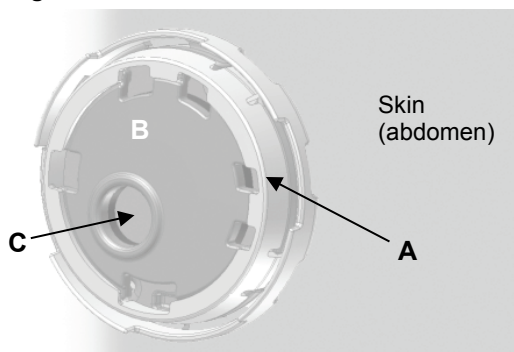
A-Tube Bumper

Dome-shaped rubber disc that sits against the stomach wall and prevents the A-Tube from pulling-out of the stomach.

1.2.3 Skin-Port

The Skin-Port is placed by a healthcare professional ~10 – 14 days after the A-Tube is placed. The Skin-Port is attached to the end of the A-Tube. A fully installed Skin-Port enables the A-Tube to be used for Aspiration Therapy. Drain pads may be inserted between the skin and the Skin-Port to maintain a clean stoma site. If used, drain pads should be replaced as needed to maintain a dry and clean stoma site.

Figure 3



A. Connector Attachment Holes

Holes in the Skin-Port face that allow teeth on the Connector to attach with the Skin-Port.

B. Skin-Port Face

Front of the Skin-Port that rotates inside the Skin-Port only when the Connector is attached and the Connector lever pushed.

C. Valve Opening

When the opening is aligned with the A-Tube opening (only during connector triggering) aspiration can be performed.

1.2.4 AspireAssist Starter Kit

The Starter Kit includes the following elements:

- A. Drain Tube (included in Tubing Set)**
Tube for aspirated stomach contents to drain out of the Companion.
- B. Connector Tube (included in Tubing Set) & Connector**
Provides Companion connection to the Skin-Port. Attaches to the Skin-Port and provides a flexible tube for aspirated food to travel to the Companion.
- C. Companion**
See section 1.2.1
- D. T-Fitting (included in Tubing Set)**
Has two barbed fittings that attach to the Connector Tube and Drain Tube, and connects to the Companion
- E. Reservoir**
Soft water bottle that can be squeezed to infuse water through the A-Tube and into the stomach or to rinse the Companion tubing.
- F. Carry Bag**
Allows storage of the Companion and its accessories
- G. Drain Clamp**
When flipped in the closed position, water can be infused and directed through the Connector Tube. The open position is selected to allow aspiration through the Drain Tube.
- H. Lanyard**
Strap that can hold the Companion around the neck.
- I. Emergency Clamp**
In case of Skin-Port disconnection from the A-Tube, the Emergency Clamp can be clamped onto the A-Tube to prevent leakage of gastric fluid and A-Tube migration into the stoma tract.

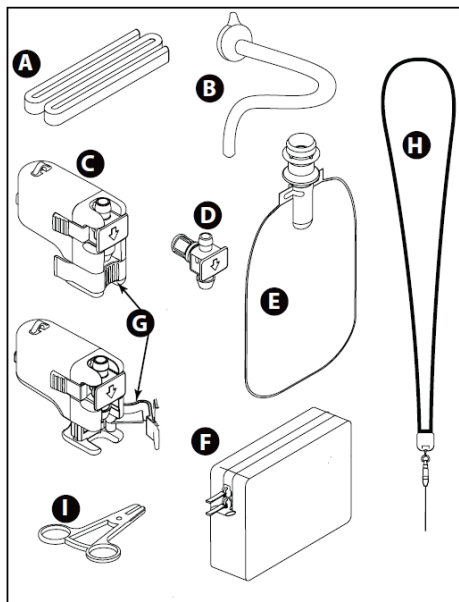


Figure 4: Companion and accessories folded up to fit in carry bag

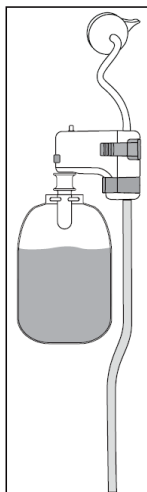


Figure 5: Assembled Companion ready for use

1.2.5 Connector

The Connector has the following features:

- A. Connector Lever**
Pushing the lever to its stop (clockwise) opens the Skin-Port valve. Returning the lever to its original position re-closes the valve.
- B. Skin-Port Engagement Features**
Provide key-ways for interlocking with the Skin-Port.
- C. Barbed Fitting**
Allows mechanical attachment to the Connector Tube.
- D. Cycle Counter**
Number displayed through a window that describes the cycles remaining. The Connector becomes disabled after 115 cycles.

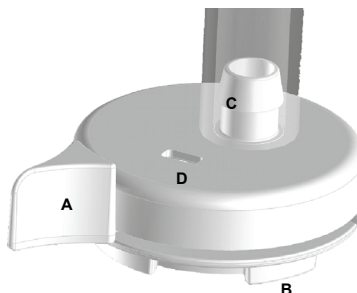


Figure 6

After the connector reaches 115 cycles, your physician or study coordinator will provide you with a replacement connector.

1.3 CHECKLIST FOR ASPIREASSIST STARTER KIT

Before first use, confirm that you received the following equipment:

- ☐ 1 – Skin-Port (*Installed by healthcare professional with Skin-Port Installation Kit, included*)
- ☐ 1 – Companion
- ☐ 1 – Connector
- ☐ 1 – Tubing Set (includes Connector Tube, Drain Tube, and T-Fitting)
- ☐ 1 – Lanyard
- ☐ 2 – Reservoirs
- ☐ 1 – Emergency Clamp
- ☐ 1 – Carry Bag
- ☐ 1 – Aspiration Journal
- ☐ 1 – User's Manual

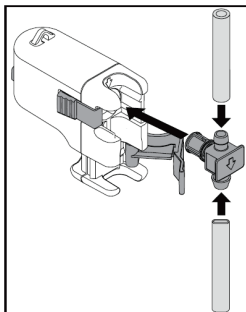
2 – System Operation

Before the first use of the Companion, the tubes and lanyard will be cut to custom length by the physician or study coordinator.

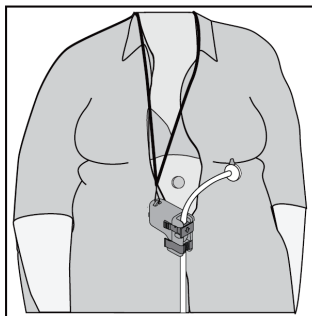
☑ **Caution:** The Emergency Clamp should be stored in the carry bag at all times. If the Skin-Port becomes disconnected from the A-Tube at any time, immediately attach the Emergency Clamp to the A-Tube to prevent leakage of stomach contents and A-Tube migration in the stoma tract. Seek medical attention immediately for re-attachment of the Skin-Port.

2.1 COMPANION SET-UP

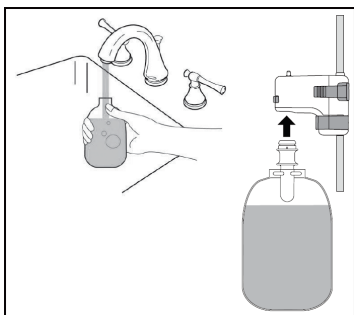
Procedures:



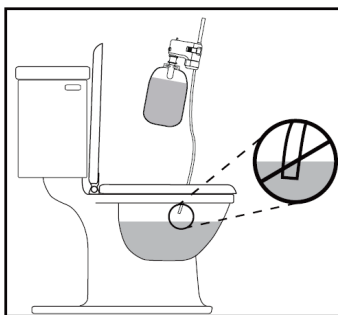
Step 1: Attach the Connector Tube and Drain Tube to the T-Fitting, then insert into the Companion with the arrow pointing down.



Step 2: Hang the Companion around the neck using the lanyard (neck strap); ensure it is adequately secured.



Step 3: Fill the reservoir with water and insert the Reservoir into the fitting on the bottom of the Companion until you hear a "click", which signals complete attachment.

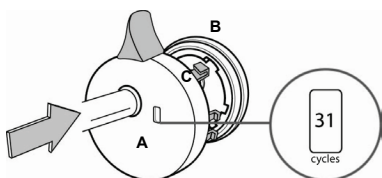


Step 4: Position Drain Tube in toilet, above water.

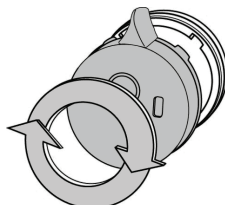
2.2 CONNECTION TO THE SKIN-PORT

☑ **Caution:** If the Companion is set to the drain mode (i.e. Drain Clamp open) aspiration will automatically begin once the Connector is attached to the Skin-Port and its lever fully pushed clockwise, so ensure that the Drain Clamp is closed before connecting the Connector to the Skin-Port.

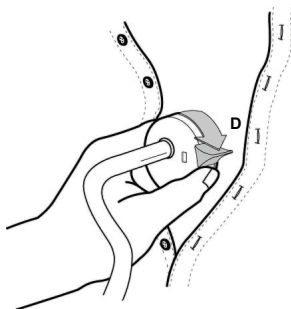
Procedure:



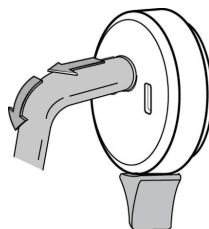
Step 1: Push Connector (A) onto Skin-Port (B) until the Connector “feet” (C) contact the face of the Skin-Port.



Step 2: Gently turn the Connector clockwise until the “feet” fall into the port holes and the Connector fits into the Skin-Port like a puzzle.



Step 3: Hold the Connector tightly with one hand and use the other hand to push the Connector lever (D) clockwise around the Connector. **Do not force the lever. If it does not turn easily, disconnect and start over.**



Step 4: Continue to push the Connector lever until it reaches a stop, at which point the Skin-Port valve is fully open. **Connector will not be fully open until the Connector lever is FULLY turned, about ¼ turn past the “click”**

Note: The Connector counts down, so it should display a cycle count one number less than prior to attachment. The left counter digit will be displayed in red when there are 19 cycles left, indicating that the Connector will need to be replaced soon. When the Counter reads “00”, you have completed 115 cycles and a new Connector must be obtained. If you continue to use the Connector, it will then read “-9” and become disabled to prevent future use.

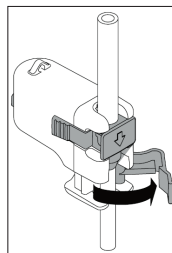
2.3 COMPANION OPERATION

☑ **Caution:** You must be in a **standing position** with the Companion below the Skin-Port for the system to operate.

⊗ **Warning:** Stop water infusion immediately if you unexpectedly start to cough. An overfull stomach could cause fluid to enter your lungs.

Procedure:

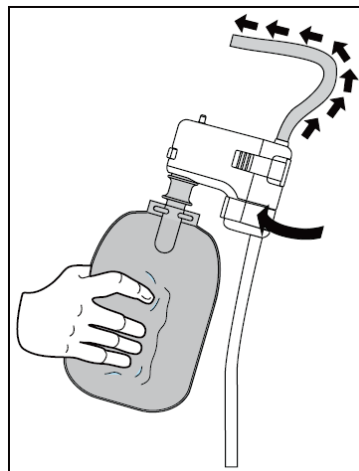
Step 1: Open the Drain Clamp to start aspiration. Stomach contents should drain out of Skin-Port, through the Connector Tube, and down the Drain Tube into the toilet.



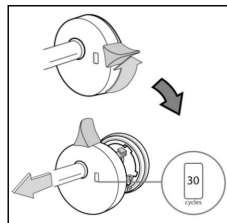
Step 2: When flow stops, close the Drain Clamp then squeeze the Reservoir to infuse water into the stomach. Use as little water as possible to clear the drain path (usually about a quarter of the Reservoir) to avoid an overfull stomach, which may be uncomfortable.

☑ **Tip:** *Try changing body position or squeezing abdominal muscles to re-start flow prior to infusing water.*

Step 3: To restart draining, open the Drain Clamp. Repeat Steps 2 and 3 as necessary.



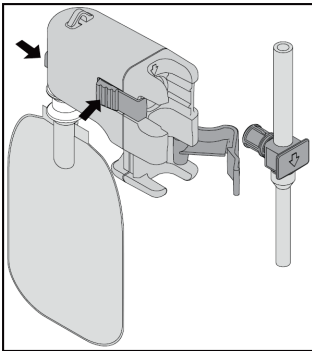
Step 4: After the stomach feels empty, push the Connector lever counter-clockwise until it reaches a stop. The Connector can then be pulled away from the Skin-Port.



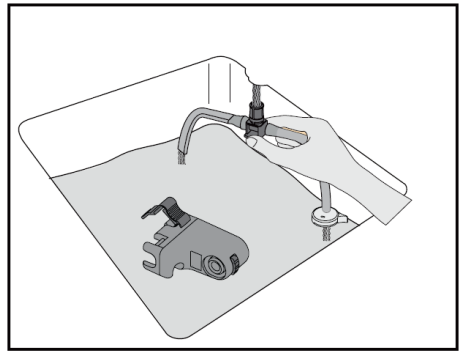
2.4 COMPANION DISASSEMBLY AND CLEANING

AFTER EACH USE

☑ **Caution:** Companion, Connector Tube, Drain Tube, and T-Fitting should be rinsed after each use by following the procedure below. The device should NOT be connected to the Skin-Port during this procedure.



Disassembly: Open Drain Clamp and press Tubing Release button to remove T-Fitting and tubing. Press reservoir release button to release Reservoir.



Rinse: Rinse all components in the sink and run clean water through the tubing. Shake off excess water and wipe equipment dry with a clean towel, then store in carry bag.

DAILY CLEANING

The Companion should be **cleaned at least once per day** as follows. The device should NOT be connected to the Skin-Port during this procedure.

1. Fill the Reservoir with warm water and a small amount of dish soap and attach it to the device.
2. Attach the T-Fitting, Connector/Connector Tube and Drain Tube to the device.
3. Close the Drain Clamp and hold the device over a sink. Squeeze the Reservoir until approximately 1/3 of the soapy water from the Reservoir has been pumped out through the Drain Tube and into the sink.
4. Open the Drain Clamp. Squeeze the Reservoir again and allow the remainder of the Reservoir to be pumped out through the Drain Tube and into the sink. Note that water will also flow out through the Connector Tube during this step.
5. Fill a clean Reservoir (or thoroughly rinse the one from above) with drinking water and repeat steps 3 & 4. Repeat as necessary.
6. Rinse all components with water to ensure that all soap / bubbles have been removed.
7. Disconnect the tubing, shake to let water run out, and store it in the carry bag.
8. Wipe down the outer housing as necessary and store the entire device in its carry bag.

OCCASIONAL CLEANING

A diluted vinegar soak can be used as needed to clean and deodorize the Companion and accessories. Do not clean the Connector with vinegar, as it could cause damage to the Connector.

1. Soak the Companion, Reservoir, T-Fitting, Connector Tube, and Drain Tube in a mixture of equal parts household vinegar (distilled white vinegar) and water overnight.
2. Rinse all components in water thoroughly before using.

☑ Caution: Do not use the following solvents for cleaning the Aspiration Device: butyl alcohol, ethanol, Freon, bleach, acetone, hydrogen peroxide, or household/multi-purpose cleaners other than dish soap and diluted vinegar. Use of any of these solvents may lead to breakdown of plastic components and labeling. Use of any of these solvents may result in infusion of harmful chemicals into the stomach.

☑ Caution: Never expose the Companion, Reservoir, or accessories to excessive heat such as a dishwasher or very hot water.

2.5 SKIN-PORT AND SITE CLEANING INSTRUCTIONS

The Skin-Port does not require special cleaning procedures. After each aspiration session, use tissue paper to dry any excess fluid in the Skin-Port hole. During daily bathing, use soap and water to gently wash the Skin-Port and the skin underneath the Skin-Port. The skin should be thoroughly dried afterwards with a clean towel. The site should be kept as dry as possible at all times (except for bathing). Do not use creams or powders around the A-Tube insertion site.

2.6 A-TUBE CLEANING INSTRUCTIONS

The A-Tube does not require special cleaning procedures. Flushing the A-Tube after each use using the water infusion instructions detailed in the Companion Operation section is sufficient to maintain a clean and functional A-Tube. After aspiration, always flush the A-Tube with water immediately prior to removing the Connector.

2.7 IN CASE OF DIFFICULTY

Breakage or Failure

If any part of the device breaks or fails to operate correctly, discontinue use of the aspiration device and immediately contact your physician.

Clogging

If the A-Tube appears to be clogged, fill the reservoir with warm water or a non-caloric carbonated beverage such as diet cola, and infuse water in short pulses into the stomach to attempt to dislodge the trapped particles. Alternatively, empty the reservoir and reconnect, then squeeze the reservoir quickly to infuse short bursts of air into the A-Tube. If the A-Tube cannot be cleared by water, air, or carbonated beverage infusion, contact your physician to have the A-Tube unclogged.

☑ Caution: Do not use objects (e.g. wires, brushes, or other mechanical devices) to clean or unclog the A-Tube or Skin-Port. Using such objects might cause injury or damage to the components.

Irritation

If you notice increased irritation, redness, discharge, or pain around the skin underneath the Skin-Port at any time, contact your physician immediately. It could be a sign of infection or A-Tube migration in the stoma tract.

2.8 ACCESSORIES REPLACEMENT

Connector

The Connector must be replaced after 115 cycles. The left counter digit will be displayed in red when there are 19 cycles left, indicating that the Connector will need to be replaced soon. When the Counter reads “00”, you have completed 115 cycles and a new Connector must be obtained through your study site. If you continue to use the Connector, it will then read “- 9” and become disabled to prevent future use. A new connector will be provided through your physician or coordinator. To replace the Connector, detach the Connector from the Connector Tube, and attach the new Connector to the tube.

Tubing Set

The Tubing Set, which includes a Connector Tube, Drain Tube, and T-Fitting, may be replaced periodically as desired, due to accumulated odor or discoloration that cannot be removed using the cleaning methods described in this manual. Each new Drain Tube and Connector Tube should be cut to the appropriate length before use. See Section 2.1 for tubing assembly instructions.

2.9 A-TUBE REPLACEMENT

The A-Tube is designed to withstand the acidity of the stomach as well as the temperature of the body without deterioration. The majority of patients will have the same A-Tube for one year or more. However, each patient is unique and based on diet, lifestyle and health considerations, the A-Tube may need replacement more frequently. In some cases, tubes may require replacement after 9 months. Tube replacement is a similar endoscopic procedure to the initial tube placement, however recovery is typically not as uncomfortable because the stoma is already established and healed.

3 – Safety Information

Users should become familiar with the following Warnings and Cautions:

3.1 WARNINGS

- You **MUST** return to your physician’s office for all scheduled follow-up visits while using the AspireAssist. Failure to have medical monitoring while using the system could lead to serious complications and possibly death. During Aspiration Therapy the physician will monitor you for low potassium and anemia.
 - Low potassium might occur with repeated aspiration of gastric contents. In the event that this occurs the treatment is typically a potassium chloride supplement and a proton pump inhibitor such as Prilosec.
 - You might also become anemic. This may be caused by getting less iron from what you eat as a result of smaller meal sizes and aspiration of a portion of the meal. In general, a low calorie diet and weight loss can be associated with iron deficiency; if Prilosec is taken this can result in iron

deficiency; and finally iron loss can be caused by increased menstruation, which often occurs with weight loss in women. Again the physician will monitor iron levels and determine whether iron supplements are needed.

- You **MUST** perform Aspiration Therapy after all or most meals. As you lose weight, the length of the external A-Tube will be permanently shortened by a healthcare professional. Eating meals without aspiration therapy could lead to weight re-gain. If a lot of weight is regained, part of the A-Tube could pull out of the stomach due to the tube being too short for the additional belly fat. If this occurs, a surgical procedure may be required to remove the entire A-Tube. If you re-gain more than 5% body weight that you previously lost at an earlier follow-up point, your physician may determine that you have become non-compliant with the therapy and the A-Tube may need to be removed.
- You **MUST** return to your physician if the Skin-Port begins to feel tight for any reason, including weight gain or improper initial installation, while you are in any position (seated, standing, etc). Excessive tension on the A-Tube from the Skin-Port could cause part of the A-Tube to pull out of the stomach.
- You **MUST** notify your physician immediately and undergo device removal as soon as possible if you become aware of being pregnant.
- Solely perform Aspiration Therapy 20 – 30 minutes after eating the three (3) major meals per day. Excessive aspiration could lead to serious complications.
- Only fill the Reservoir with clean water. Use of contaminated water or other liquids could harm your stomach.
- If taking prescription medicine, please consult your physician to determine if the dose should be changed with weight loss.
- Do not manipulate the A-Tube or Skin-Port at any time after installation. Excess tension or torque on the A-Tube or Skin-Port can result in enlargement of the stoma tract resulting in gastric leakage, or movement of the internal bumper resulting in tissue damage.
- Do not take medication with meals that are aspirated because you may not get the appropriate dose of medicine. Take oral medications at least 2 hours prior to performing Aspiration Therapy.
- The Emergency Clamp should be stored in the carry bag at all times. If the Skin-Port becomes disconnected from the A-Tube at any time, immediately attach the Emergency Clamp to the A-Tube to prevent leakage of stomach contents and A-Tube migration in the stoma tract. Seek medical attention immediately for re-attachment of the Skin-Port.
- Do not engage in any activities that are below 5-ft of water (scuba diving, etc.) while the A-Tube is implanted.
- The Companion device should be thoroughly washed at least once each day to avoid bacteria growth within the device itself, or its accessories.
- Do not insert any foreign objects between the Skin-Port and the skin because this can damage to the A-Tube.
- Avoid carrying packages/objects against the abdomen. Excessive weight on the Skin-Port could cause damage or irritate the skin around the A-Tube.
- If the device leaks stomach content onto your skin, rinse the affected area with water to prevent skin irritation.
- Stop water infusion immediately if you unexpectedly start to cough. An overfull stomach could cause fluid to enter your lungs.

- Do not attempt to open the Skin-Port valve by any other means besides the Connector. If the Skin-Port valve is left partially opened because of non-recommended manipulation, stomach contents can leak and cause skin irritation.
- If you notice increased irritation, redness, discharge, or pain around the skin underneath the Skin-Port at any time, contact your physician immediately. It could be a sign of infection or A-Tube migration in the stoma tract.
- If you experience severe nausea or diarrhea at any time, contact your study team immediately. Severe nausea or diarrhea can lead to severe dehydration and injury if not treated immediately.

3.2 CAUTIONS

- You must be in a standing position with the Companion below the belly for the system to operate.
- If the Companion is set to the drain mode (i.e. Drain Clamp open) aspiration will automatically begin once the Connector is attached to the Skin-Port and its lever fully pushed clockwise, so ensure that the Drain Tube is properly positioned over a toilet or collection container before connecting the Connector to the Skin-Port.
- Before the first use of the Companion, the tubes and lanyard will be cut to custom length by a healthcare professional.
- Only the Connector should be directly attached to the Skin-Port.
- Verify that both the Companion and Skin-Port do not have any damage before connecting each together to start aspiration.
- Do not attempt to take apart the Companion. Tampering with the Companion could cause the device to function incorrectly.
- Use caution when attaching or disconnecting the Connector to the Skin-Port. If the Connector lever gets jammed, do not push harder. Remove the Connector and start the process over. Consult your study coordinator if the problem persists.
- Lubricants are not required for operation of the device, but if implemented, only use water-based lubricants.
- The Connector only functions for 115 cycles (i.e. connections to the Skin-Port.) You must ensure that you have a replacement Connector before completing 115 cycles or the Skin-Port valve and Connector will no longer function until replaced by a new Connector.
- Companion, Connector, and Tubing Set should be rinsed after each use by following the procedure in this manual.
- Prior to the 1st use of the device, conduct a pre-check of the device and operation under the supervision of a trained medical professional.
- Do not use the following solvents for cleaning the Aspiration Device: butyl alcohol, ethanol, Freon, bleach, acetone, hydrogen peroxide, or household/multi-purpose cleaners other than dish soap or diluted vinegar. Use of any of these solvents may lead to breakdown of plastic components and labeling. Use of any of these solvents may result in infusion of harmful chemicals into the stomach.
- Never expose the Companion, Reservoir, or accessories to excessive heat such as a dishwasher or very hot water.

- Do not use objects (e.g. wires, brushes, or other mechanical cleaning devices) to clean the A-Tube or Skin-Port. Using such objects might cause injury or damage to the components.

3.3 SYMBOLS

	Authorized representative in the European community		Caution, consult accompanying documents
	Catalog number		Consult instructions for use
	Serial number		Use by date
	Do not reuse		Date of manufacture
	Batch code		Manufacturer

LAST PAGE