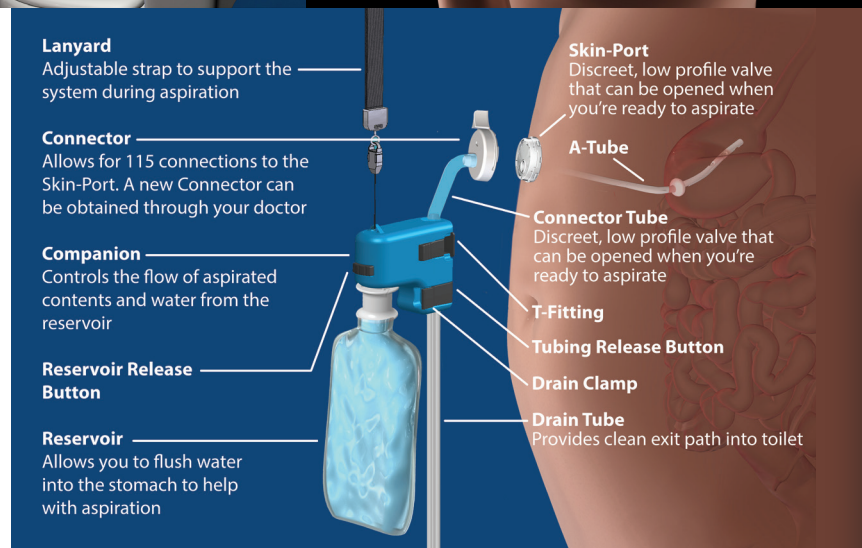


# Recently Approved Weight-loss Device: AspireAssist™

by Shelby Sullivan, MD



**E**ndoscopic Bariatric Therapies (EBT) are emerging as new treatment options for patients who have not been able to lose weight with lifestyle therapy, and either don't qualify for – or don't want – bariatric surgery. These therapies come in the form of devices or procedures that are placed or performed endoscopically, which means that they are done through the mouth using an endoscope. In general, these procedures have significantly less risk than bariatric surgery and don't require an overnight stay in a hospital. Two EBT's (both intragastric balloons) were approved by the Food and Drug Administration (FDA) last year. And, earlier this year, the FDA approved the new AspireAssist™ (Aspire Bariatrics, King of Prussia, PA) – a brand new class of EBT.



Photos Courtesy of Aspire Bariatrics

## What is the AspireAssist™?

The AspireAssist™ is a new device allowing the patient to perform aspiration therapy that removes a portion of the calories consumed after a meal. The AspireAssist™ device is comprised of two sets of components:

- One set that is implanted in the patient
- The other set which is attached to implanted components only during aspiration

The set of components that is implanted in the patient is comprised of (1) the A-Tube™ - a soft, flexible silicon tube that is placed in the stomach and crosses the abdominal wall to the surface of the skin, and (2) the Skin-Port™ - a plastic disc that attaches to the A-Tube™ and keeps it closed between aspiration sessions.

The components used only during aspiration include:

- The Connector, which attaches to the skin sport and allows the skin port to open
- The Companion™, which is a siphon containing a two-way valve that allows for both the flow of stomach contents out of the stomach and the infusion of water into the stomach
- The Reservoir, which is a 600 ml soft water bottle that attaches to the Companion™ so that can patients can flush the system during aspiration
- The Patient line, which is a flexible silicone tube which connects the Connector to the Companion
- The Drain line, which connects to the bottom of the companion and allows stomach contents to flow into the toilet

## How is the A-Tube™ placed?

The A-Tube™ is placed during an upper endoscopy – a non-surgical procedure. Patients are given mild to moderate sedatives where they are still breathing on their own. An endoscope is inserted into the patient's mouth and passed into the esophagus (swallowing tube) and then into the stomach. A full exam is performed to make sure that there are no reasons to prevent safe placement of the A-Tube™. The location of placement is then verified by light shining from the endoscope through the abdominal wall, and from indentation into the stomach seen with the endoscope as the finger is pushed into the abdomen from the A-Tube™ placement location. The skin at the A-Tube™ placement location is then cleaned, and a needle is used to inject a local numbing medication (like lidocaine).

Once that is complete, a small half-inch cut is made on the skin and a needle is placed through it that cuts into the stomach. Then, a guidewire is placed into the stomach which is grabbed by the endoscope and pulled out through the mouth. Once the guidewire is out, the A-Tube™ is attached and the guidewire is pulled from the skin side until the A-Tube™ is in place in the stomach, with a portion extending out through the skin cut. One week after the A-Tube™ placement, the Skin-Port is attached and is ready for use by the patient for aspiration therapy.

## What is aspiration therapy?

Aspiration therapy is the process of removing up to 30 percent of the calories eaten in a meal, combined with a lifestyle therapy weight-loss program. Twenty minutes after a meal, patients with the AspireAssist™ perform aspiration therapy through the following steps:

1. Go to the restroom.
2. Fill the Reservoir with tap water.
3. Attach the Connector to the Skin-Port, thus opening the Skin-Port.
4. Open the valve on the Companion to allow stomach contents to flow out.
5. Close the valve and flush with water from the reservoir into the stomach.
6. Detach the connector from the skin-port after aspiration therapy is complete. Steps four and five can be repeated to ensure aspiration therapy has been adequate.

## How does aspiration therapy cause weight-loss?

Aspiration therapy helps people to lose weight through two mechanisms:

1. Patients remove up to 30 percent of the calories consumed at a meal when they aspirate.
2. Patients eat less during a meal in order to facilitate aspiration.

Previous studies have shown that aspirating calories alone does not account for all of the weight-loss. In addition, patients must change meal-time behaviors in order to successfully aspirate and to avoid getting food stuck in the A-tube. These behaviors include:

1. Chewing food slowly until it falls apart in the mouth before swallowing
2. Cutting food into very small pieces
3. Avoiding foods that get stuck in the tube such as red meat
4. Drinking a lot of water with meals

Patients report that they eat less food at meals because of these behavior changes. They can also see what comes out of the drain tube, and often report that unhealthy foods such as hamburgers or French fries have an unappealing appearance during aspiration. Healthier foods, on the other hand, do not. This is an additional way in which the AspireAssist™ supports healthy food choices.

## What are the results of this therapy?

In the United States multi-center trial called the PATHWAY study, which featured 171 patients, the patients who completed one year of aspiration with the AspireAssist™ and lifestyle therapy lost 14 percent of their total body weight. However, those patients who received lifestyle therapy alone only lost five percent of their total body weight. The most common side effects of the AspireAssist™ are pain immediately following placement (which usually resolves in one to four weeks), and granulation tissue (an irritation) that can develop in the tract of the A-Tube™.

## Q&A with AspireAssist™ Patient, Anna Lotta Frisk Bosnyak

*Anna poses for the camera in her hometown of Malmö in Sweden.*

### What other treatments have you tried before AspireAssist™?

I've tried almost all methods on the market to lose weight: commercial programs, shakes and soups, Atkins, banana-diet, fasting, etc. You name it – I've tried it! I also had a dialogue with my primary doctor for years, and he really tried to help me.

### What made you decide to choose the AspireAssist™?

I knew that I couldn't do it with any other method, but I wanted to try anything that could help me lose weight. Aspire Assist was new, so there wasn't really anybody I could ask about it. I listened to my friend, who is the one who started the study in Sweden. He said "I am going to be patient number one. If you like, you can be patient number two." It was not a hard decision to make. It seemed pretty easy to handle and, as I understood, it did not have any side effects.

### What would you tell someone else who is considering this device?

When you struggle with weight issues and surgery seems like one of your last options, I think most people will find AspireAssist to be a pretty simple method. I myself lost 150 pounds during my first year after getting it. You're still getting all of your normal nutrition the way you usually would, and you may not have to stay on medication for the rest of your life. The procedure is also reversible, so you can remove it. Your social life is not going to change because of the device. Having the device helps you to eat slower because you have to take the extra precaution to chew your food thoroughly, and that will also help you boost your metabolism. And, if you need support, you have access to it all the time. You are able to see a nurse regularly, and there are people with experience to answer any question you might have.

*Photo Credit: Karin Odhner*



## Who qualifies for the AspireAssist™?

The AspireAssist™ is approved for patients 22 years and older with a Body Mass Index (BMI) of 35-55 kg/m<sup>2</sup>, who have tried to lose weight through lifestyle therapy programs but were unable to either lose weight or maintain their weight-loss. This therapy is not approved for patients who have bulimia, binge eating disorder or night eating syndrome. It is also not approved for patients who have had previous Roux-en-Y Gastric Bypass or Sleeve Gastrectomy.

## Conclusion

Aspiration therapy using the AspireAssist™, in conjunction with a lifestyle therapy program, can be a suitable long-term solution for weight-loss in people who have tried other methods that haven't worked or who don't want bariatric surgery. Continuing with lifestyle therapy and making behavior changes at meal times are both keys to successful weight-loss with this therapy.

### **About the Author:**

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## What has life been like with the device implanted?

The device itself does not bother me at all. I don't go to the beach wearing a bikini though, but that's not something I'll miss because I didn't do that before. Sometimes, there can be a little leakage from the hole where the tube comes out, but all I have to do is wrap a facial tissue around it about twice a day. If I go away overnight, I carry a small overnight bag with me that has all of the tools I need. During the "weight-loss period," I flushed 20 minutes after every meal. Now, during my weight maintenance period, I only use it before bedtime.

In addition, I've learned how to eat properly. I really need to chew my food very carefully, so it takes longer for me to eat now. It's not fun to chew on junk food, so the quality of my food has also improved. Because it takes longer for me to eat, my brain has a chance to alert me when I'm full. Before, I used to shuffle my food in very fast. Now, I realize when I've had enough to eat and I'm ready to stop. I will also say that I've gained my life back. Due to being overweight, I didn't have much of a life before. I was so sick, depressed and affected deeply by my weight. I was diagnosed with and medicated for hypertension, depression, Type 2 Diabetes and chronic pain. After a while during my weight-loss period, I was able to get off of my pills, and today I don't need anything! That's such a relief! The energy and strength in my body is so much greater. I also don't need to hide anymore because of the shame I used to feel. I can shop for clothes in ordinary shops!

## What was the procedure like to get the device?

The procedure was very easy – an ordinary endoscopy that takes about 15 minutes. You aren't sleeping through it, but you're given a drug that helps you to relax and take your mind off of what's going on. When you "wake up," you can go home. Some patients have more pain afterward in the area where the procedure was done, but your doctor may prescribe medication to help with the pain.



# ABOUT THE OBESITY ACTION COALITION (OAC)

The Obesity Action Coalition (OAC) is a National non-profit organization dedicated to giving a voice to individuals affected by obesity and helping them along their journey toward better health. Our core focuses are to elevate the conversation of weight and its impact on health, improve access to obesity care, provide science-based education on obesity and its treatments, and fight to eliminate weight bias and discrimination.



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The OAC knows that the journey with weight can be challenging but we also know that great things happen when we learn, connect and engage. That is why the OAC Community exists. Our Community is designed to provide quality education, ongoing support programs, an opportunity to connect, and a place to take action on important issues.

### Through the OAC Community, you can get access to:

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