## FAO: ASPIRE ASSIST®

#### Does insurance cover it?

No, insurance does not cover placement or maintenance of the Aspire Assist® device. However, we may be able to submit a claim to your insurance after the Aspire is placed. There is no guarantee of coverage, though partial reimbursement (up to 80%) has been achieved in select cases.

## Why doesn't insurance cover it?

At this time, the Aspire Assist® is considered an "elective" procedure, even though it can be expected to reduce or reverse high blood pressure and diabetes as you lose weight.

## When did this procedure become approved by the FDA?

June 14, 2016

## Who can get the Aspire Assist®?

The Aspire Assist® is appropriate for people 22 and older who are obese, with a body mass index of 35 to 55, and who have failed to achieve and maintain weight loss through non-surgical weight-loss therapy. It is not appropriate for people who have an eating disorder. Your doctor will screen you for symptoms of an eating disorder.

## Does it hurt to have the device placed?

There is some post-procedural discomfort. It is easily controlled with oral pain medications for a few days after the procedure. Your doctor will prescribe medication to make you comfortable.

## How long does it take to place the Aspire Assist®?

The device is placed during an endoscopic procedure and takes about 15 minutes. You will be asleep and comfortable during the procedure.

## How often do I have to come in to the office after the procedure?

You will be seen in the office 2 weeks after placement of the A-tube to convert the tube to a close-fitting aspiration "port." You will be instructed on use of the aspiration kit at that time. You will then be seen approximately every 4-6 weeks so that we can check your tube, monitor your weight loss progress, and obtain periodic blood electrolyte levels.

## Where is the port? Can people see it?

The port will be right up against the skin of your abdomen. It is not noticeable under clothing.

#### Can the tube site become infected?

The Aspire Assist® is placed during a sterile procedure but there is a small risk of infection. Your doctor will use antibiotics during the procedure and immediately afterward to reduce this risk. It is normal for the tube to leak some green or yellow "goo." This is the body's natural healing process and does not mean you have an infection. Your doctor will help you to determine if there is infection if you are concerned.

## How often do I use the device to aspirate my stomach contents?

It is recommended to aspirate after each meal, which is typically 2-3 times a day. We advise against eating snacks between meals. After you have reached your weight loss goals, and have learned healthier eating habits, you may be able to reduce the frequency of aspirations.

## Will I get hungry after I've aspirated?

No. You are only removing 30% of the food you ate, and because you wait 20 minutes after eating to aspirate, your stomach has already signaled to your brain that you are full.

## Where does the aspirated food go?

You will drain it straight into the toilet and flush it away.

#### How long does the A-tube stay in?

There is no time limit for how long the A-tube can be in use. Many people keep it for a while after their weight loss goals have been met as "insurance," until they feel comfortable that they have learned how to eat correctly and exercise and will not put the weight back on.

## How much weight will I lose?

It is important for you to understand that the Aspire Assist® is a tool to aid weight loss and must be used in conjunction with diet, exercise, and a behavior modification program. The amount of weight you lose and maintain will depend on how closely you follow your diet and adopt long-term lifestyle changes. For motivated patients, weight loss can be equivalent to gastric sleeve bypass surgery. In the US clinical trial, the most successful patient lost over 100 pounds in one year. In the study, patients lost 3 times more weight than those using diet and exercise alone.

#### What if the tube falls out?

The A-tube is held securely in place, but if it comes out, your doctor will replace it in the office in a quick, painless procedure that does not require sedation. It is important for you to tell your doctor immediately if the tube comes out.

## If I lose weight, won't the tube stick out too far?

As you lose weight, the doctor will trim your A-tube so that it stays right up against your abdominal wall.

# It seems like the Aspire device would allow people to "purge" what they eat. Isn't this similar to bulimia?

No. It is not possible to binge eat with this device. The tube will only work if you eat extremely slowly, chew your food into fine bits, and drink plenty of fluids. Over time, this leads to healthier eating habits. In fact, up to 20% of the weight loss that people achieve is due to the changes in how they eat, not just the act of aspirating. If you were to eat too rapidly, the tube could potentially clog or malfunction. In the U.S. trial of Aspire Assist, no patients with the device developed bulimia.