Cary Gastroenterology Associates

# PATIENT CONSENT TO ASPIREASSIST PROCEDURE

As a patient, you must be adequately informed about your condition and the recommended procedure. Please read this document carefully and ask about anything you do not understand. Please initial each page and sign this document at the end to indicate your understanding and acknowledgement of its content.

**1. Consent.** I consent to have Dr. Shannon Scholl/Dr. Christopher McGowan perform the AspireAssist procedure to treat my obesity.

**2. Purpose of Procedure.** The purpose of this procedure is to implant the AspireAssist gastrostomy tube in my stomach to enable me to remove a portion, or aspirate, of the contents of my stomach after eating. I understand that I will need to chew very thoroughly and aspirate 3 times per day to achieve the best results. If I do not chew thoroughly, I may not be able to aspirate effectively and therefore may not lose as much weight

**3. Description of Proposed Procedure.** The AspireAssist procedure is typically performed using conscious sedation and local anesthetic to keep you comfortable and relaxed. However, depending on your individual medical history and health, your doctor may decide to use general anesthesia. This decision may be made in advance of the procedure, or during the procedure. Once the sedation/anesthesia is started, your doctor will insert an endoscope, a thin flexible tube with a tiny camera at the end, into your mouth and down into your stomach to see inside your stomach. Your doctor will make a small ½ inch (1 cm) cut on your abdomen to allow a thin wire to be passed through this incision and out of your mouth. Your doctor will insert the A-Tube through your mouth, into your stomach, and out through your abdomen until the A-Tube bumper rests against the inside of your stomach. After the procedure, you will have a long tube coming out of your abdomen. The new opening in your abdomen where the A-Tube is placed is called a stoma. This tube will be held onto your abdomen with tape to keep it in place while the stoma heals. The tube will be shortened to the surface of your skin about 1-2 weeks after the procedure.

**4. Benefits of Proposed Procedure.** The AspireAssist has been shown in a randomized US clinical study to enable patient to achieve significantly more weight loss than patients assigned to the control group. Scientific research shows that weight loss in obese patients with type 2 diabetes helps to control the disease. Research also shows that weight loss improves the major risk factors for heart disease, such as high bad cholesterol (HDL), low good cholesterol (LDL), and high blood pressure. Other benefits of the AspireAssist are that it is a 15 minute outpatient endoscopic procedure, so no surgery is needed. The A-Tube can be taken out at any time with a brief endoscopic procedure, and the stoma will close. With the AspireAssist, you can make slow and steady changes to your diet and exercise routines while you are losing weight. Lifestyle counseling is provided to help you make those changes at your own pace.

**6. Alternatives.** I understand that surgical and non-surgical alternatives for the treatment of obesity exist. Non-surgical alternatives for the treatment of obesity include dieting, exercising, counseling and medication. Surgical methods include roux-en-y gastric bypass, gastric banding, and sleeve gastrectomy. I understand that other procedures and treatment options exist and I have elected this procedure.

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**6. Potential Risks and Side Effects**

***I understand and accept the risks related to the percutaneous endoscopic procedure, including but not limited to the following:***

*Likely risks*

- Discomfort
- Sore throat
- Pain
- Abdominal bloating
- Nausea/vomiting
- Indigestion

*Less likely or rare risks*

- Bleeding
- Infection
- Hypoventilation
- Peritonitis
- Aspiration pneumonia
- Sedation complications
- Perforation
- Death. Although death is expected to be extremely rare with this procedure, I understand that there is always a possibility of death with any endoscopic procedure. No deaths occurred during the US clinical trial.

***I understand and accept the risks related to the stoma site, including but not limited to the following:***

*Likely risks*

- Abdominal discomfort/pain
- Peristomal skin irritation/ inflammation
- Erythema and granulation tissue

*Less likely or rare risks*

- Peristomal leakage and/or bleeding
- Stoma site infection
- Buried bumper syndrome
- Persistent fistula after tube removal
- Skin induration

_____ *(initials)*

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***I understand and accept the risks related to the aspiration process, including but not limited to the following:***

*Less likely or rare risks*:*

- Occasional indigestion
- Nausea
- Vomiting
- Constipation
- Diarrhea

*In the US Clinical Study, a similar percentage of people in the AspireAssist group and in the control group experienced these side effects.

**7. Additional Information.** The AspireAssist Patient Guide provides additional information on the risks and side effects and the percent of patients in the US Clinical Study who experienced them, if any. This guide can be accessed online at **aspirebariatrics.com/patient-guides**. I understand that it is my responsibility to fully review the AspireAssist Patient Guide before my procedure, and to ask my doctor for a paper copy of the guide if I am unable to access it online.

**8. Guarantees.** I understand that the result of the procedure is not guaranteed. There is a possibility that the physician will determine that the A-Tube cannot be safety placed after beginning the endoscopic procedure. In the US Clinical Study, this occurred in one patient, and the decision was made before any incisions were made. I understand that before, during, or after I may develop new conditions. These new conditions may require other procedures to be used. I authorize my doctor(s), the assistant(s), and the hospital staff to use these other procedures as reasonably necessary and appropriate for my care, including blood transfusion products.

**9. Aftercare.** I understand that medical follow-up and aftercare is essential to my safety and weight loss success. Medical follow-up is important for checking my blood levels, stoma site, aspiration progress, and general health. Nutritional counseling is vital to success during AspireAssist therapy to help me make gradual healthy changes to my lifestyle.

**10. Women with Childbearing Potential**. I understand that the AspireAssist has not been studied in pregnant women. If I decide that I would like to become pregnant once the A-Tube is placed, I understand that I must have my A-Tube removed before attempting to become pregnant. If I become pregnant while my A-Tube is in place, I understand that I must tell my doctor right away. My AspireAssist doctor and my obstetrician will develop a plan to remove the A-Tube that is as safe as possible for me and my baby.

**11. Additional Procedures.** I understand that during the course of therapy, unforeseen conditions may by encountered that require additional procedures. These unforeseen conditions may also necessitate removal and/or replacement of the A-Tube.

**12. A-Tube Replacement.** I understand that the AspireAssist is intended for long-term use, but it will need to be replaced from time to time due to breakdown of the tube. The majority of patients will have the same A-Tube for one year or more.

_____ *(initials)*

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**13. Cancellation of Procedure:** I understand that unforeseen events may occur that could result in the last minute cancellation or postponement of my procedure. If, for any reason, I cancel my procedure with less than a 7 day notice, or fail to present for my procedure, I will incur a nonrefundable charge of $1,000 for failure to provide adequate notice of cancellation.

**I have read this document thoroughly and have had any and all questions answered to my satisfaction and understanding. I understand and acknowledge the contents and significance of this consent and give my informed consent to proceed with the AspireAssist procedure.**

_____

Patient's Full Legal Name

| _____ | _____ | _____ |
|---|---|---|
| Signature of Patient | Date | Time |
| _____ | _____ | _____ |
| Signature of Witness | Date | Time |