1.0 Executive Summary

The AspireAssist® is a device to assist in weight reduction in patients with moderate-risk or high-risk obesity, in conjunction with lifestyle therapy and continuous medical monitoring. It is indicated for use in adults aged 22 or older 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. Although the device is fully and readily reversible, it is intended for long-term duration of use. In conjunction with Lifestyle Therapy, the AspireAssist produces a clinical benefit comparable to bariatric surgery without the complications or ongoing side effects typical of bariatric surgery.

The AspireAssist consists of an endoscopically-placed gastrostomy tube (the “A-Tube™”), similar to a percutaneous endoscopic gastrostomy (PEG) tube, a 1” diameter low profile valve that sits on the abdomen (the Skin-Port) and a detachable external device through which patients partially drain (“aspirate”) their gastric contents into a toilet after a meal. The A-Tube is placed similarly to a PEG tube in a 20-minute outpatient endoscopic procedure, done typically under conscious sedation. At ~10 days post-gastrostomy, the external end of the A-Tube is cut to within 1 cm of the abdominal skin and attached to a Skin-Port. Patients are then trained on how to use the device and instructed to chew very thoroughly (to avoid A-Tube blockage) and to aspirate approximately 20 minutes after each of three main meals daily. Research has shown that a maximum of 30% of the caloric content of a meal is drained with this device. [Ref 1]

The AspireAssist received premarket approval by the FDA in June 2016 and is now in commercial use in a number of leading teaching hospitals in the US, including Johns Hopkins University, Brigham and Women’s, Columbia Presbyterian, and Washington University (St. Louis), as well as in a number of private clinics. It has been the subject of various clinical trials in the US, Mexico, and Europe, involving over 750 patients in aggregate. Thus far, the results of six studies have been published in the scientific literature, including (i) an 18-subject (mean baseline BMI= 42.4 kg/m²) randomized controlled trial (RCT) with results out to 2 years [Ref 1], (ii) an 11-subject “super-obese population” (mean baseline BMI= 66.2 kg/m²) multicenter observational study with results out to 2 years [Ref 2], (iii) a 25-subject (mean baseline BMI= 39.6 kg/m²) observational study with results out to 3 years [Ref 3, 4, 5, 6, 7]; (iv) a 171-subject (mean baseline BMI= 42.6 kg/m²) multicenter RCT with results out to 1 year [Ref 8]; (v) an 100-subject (mean baseline BMI= 43.2 kg/m²) comparative study of Roux-en-Y gastric bypass vs AspireAssist with results out to 1 year [Ref 9]; and (vi) a 201-subject (mean baseline BMI= 44.3 kg/m²) multicenter observational study with results out to 4 years [Ref 10, 11, 12]. Mean baseline BMI of the subjects in these studies (excluding the super-obese study [Ref 2]) was 43.9 kg/m² and mean excess weight loss of the AspireAssist subjects in these studies was 46% + 27% (95% CI: 43%, 49%) at 1-year, 51% + 29% (95% CI: 45%, 56%) at 2-years, 53% + 27% (95% CI: 44%, 62%) at 3-years, and 48% + 36% (95% CI: 25%, 71%) at 4-years. Weight loss is seen to be durable through at least 4 years. Consistent with the literature that establishes that significant health benefits accrue with even modest weight loss, AspireAssist studies have shown clinically significant improvement in blood pressure, triglycerides, HDLs, and HbA1c [Ref 3, 5, 8, 9,10].

As demonstrated by Sullivan et al [Ref 1], only 50-80% of the weight loss observed with the AspireAssist can be explained through aspiration, implying the existence of an additional mechanism of action. The authors postulate that, “the dietary changes needed for effective aspiration therapy also reinforce the
basic behavioral principles of weight management, such as increased chewing of food and drinking more water with each meal to facilitate meal aspiration, limiting between-meal snacks to avoid the need for additional aspirations, and developing a structured meal plan to accommodate aspiration inside and outside the home.” [Ref 1]. Studies have shown that the therapy does not lead to adverse eating behaviors [Ref 1, 3, 5, 8, 10], nor to compensatory eating to adjust for caloric loss through aspiration; indeed, patients have shown improved restraint, less disinhibition (more control over food intake), and decreased hunger [Ref 1].

There have been no reports of any death, any adverse event resulting in permanent or long-term impairment, any adverse event requiring surgery or other emergency procedures, or any adverse event resulting in gravely-ill patients or extensive hospitalization [Ref 1-10]. From the absence of serious complications in these studies, one can infer that the serious complication rate is less than 1% in the peri-procedural period (p<0.05) and less than 1% per year in the post-procedural period (p<0.05)- rates significantly lower than the serious complication rate associated with bariatric surgery. Complications associated with the AspireAssist were few and minor, and resolved spontaneously or with conservative therapies (antibiotics, topical lotion, or analgesics), except for a small percentage of patients (<5%) which were either hospitalized for one or two days as a result of a peri-procedural complication or required an endoscopy (<5% per year) to remove or replace the A-Tube as a result of a post-procedural complication [Ref 1-10]. Approximately 95% of the complications associated with the AspireAssist are those known to be associated with percutaneous endoscopic gastrostomy tubes, with about half of all adverse events occurring within the perioperative period [Ref 8, 10]. The most common adverse events in the perioperative period are abdominal pain and discomfort, while the most common adverse events in the postoperative period are peristomal granulation tissue. Additionally, metabolites and electrolytes have been monitored throughout these studies; there has been no evidence of clinically-significant abnormalities in electrolytes or metabolites [Ref 1,3,6,8,9,10].

Significant improvement (P <0.01) in all Quality of Life measures have been reported by AspireAssist subjects [Ref 5, 6, 8, 9]. Approximately 99% of the subjects indicated satisfaction with participating in the study and 90% would recommend the AspireAssist to family or friends interested in losing weight.

In conclusion, the AspireAssist has been shown to be an effective, durable, and safe weight loss therapy for obese patients with baseline BMIs ranging from 35-55 kg/m². The therapy is shown to be equally effective, safe, and durable in a community setting as in an investigational setting. It offers reversibility and yet is appropriate as a chronic therapy. The therapy has been well-received by patients due to its minimal invasiveness, its effectiveness, its excellent safety profile, the absence of severe complications, and the ability to control one’s own weight-loss trajectory. AspireAssist Therapy offers substantial savings, as well as predictability of costs, to the healthcare system over conventional bariatric surgery, both because of the simplicity of the procedure and its relatively few and minor complications vis a vis bariatric surgery.

From the lessons learned in the cited studies, improved screening and patient training techniques have evolved. For example, patients are now instructed to begin therapy with a soft diet, then gradually introduce foods requiring chewing to enable them to learn the degree of chewing required. With these improved screening and coaching techniques, it is likely that even better outcomes than those reported in the cited studies can be achieved.

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References:

11. Machytka, E, Forssell H, Norén E, Turro R, Bammer E, Testoni PA, Fehlert V. AspireAssist as a Tool to Treat Obesity: 1,2, and 3 years results to data in 199-Subject Multi-Center Post-Market Study,., United European Gastroenterology Journal 4(S5) A157–A720.