An Intelligent, Endoscopic Solution for Obesity
Introducing the first and only LONG-TERM & REVERSIBLE endoscopic obesity solution, with the power to address obese and super-obese patients.
These four siblings/in-laws lost 190 kgs collectively in 10 months.
AspireAssist: Dual Mechanism for Long-Term Results

30 Percent
CALORIC REDUCTION

Removes a portion of stomach contents, bypassing absorption

Integrated
INTAKE MODULATION

6mm tube diameter re-trains patient to chew extensively, naturally slowing intake
Primary Mechanism: Caloric Reduction

Allow 20 minutes after each meal for digestion

In privacy of restroom, remove AspireAssist® from pocket-sized bag

Removes up to 30% of calories, directly into toilet

Discreet port “button” when not in use

Patients aspirate after each main meal, three times per day.
Secondary Mechanism: Intake Modulation

**Increased Chewing**
(May/June 2015)

- 91% Agree
- 1.6% Disagree
- 8% Neutral

I chew my food more thoroughly since beginning therapy with the AspireAssist.

**Increased Meal Consumption Time**
(May/June 2015)

- Before: 10.6 minutes
- After: 27.5 minutes

**Reduced Calorie Consumption**
(May/June 2015)

- 47% Significantly decreased
- 31% Somewhat decreased
- 17% No change
- 1.6% Somewhat increased
- 3.1% Don’t know

Since beginning therapy with the AspireAssist, I believe the number of daily calories I eat has:

Consumption is modulated by the 6mm tube diameter.

*Patients must chew thoroughly to facilitate aspiration, training patient to eat more slowly for long-term weight maintenance.*

Lifestyle Counseling Reinforces Healthy Habits

LIFESTYLE CHANGE IS PARAMOUNT TO ASPIREASSIST® THERAPY

Drinking Water
Exercise
Mindfulness
Nutritious Choices
Support Community
Limited Snacking

All patients receive lifestyle counseling with AspireAssist therapy, typically about 10 sessions in first year
Proven Clinical Results

Mean 2-Year Weight Loss

European Composite

1 year 2 years

24kgs 26kgs

U.S. Feasibility Study

1 year 2 years

21kgs 23kgs

Comparative Results to Bariatric Surgery...

Mean % Excess Weight Loss (One Year)

AspireAssist® Gastric Band Sleeve Gastrectomy

51% 42% 55%

...with the safety profile for even high-BMI patients

Excellent Track Record of Safety

- **No serious complications after >300 patients**
- **Draws on 35 years of PEG tube best practices**
- **Excellent patient tolerance**
- **No electrolyte or metabolic imbalances**
Safe and Routine Procedure

STANDARD PEG PROCEDURE REQUIRES NO ADDITIONAL TRAINING

The AspireAssist is implanted using the Ponsky “pull” PEG technique, a simple and routine procedure for Gastroenterologists & Surgeons.

PROCEDURE FEATURES

15-MINUTE PROCEDURE
To place the tube endoscopically through the mouth

USES CONSCIOUS SEDATION
General anesthesia is typically not necessary

OUTPATIENT
Patients return home within 2 hours

HIGH PROCEDURE SUCCESS
Adequate transillumination in >99% of patients
The AspireAssist is the only endoscopic solution that is both long-term and reversible, putting the patient in the driver’s seat.

**LONG-TERM SOLUTION**

Intended for long-term use, although patients typically reduce frequency of use as they approach goal weight and adopt healthier habits.

**EASILY REVERSIBLE**

Tube can be removed at any time in a simple 10-minute endoscopy.
**Patient Acceptability**

**Strong Patient Interest in AspireAssist**
(International Market Research 2014)

<table>
<thead>
<tr>
<th>Country</th>
<th>USA N=203</th>
<th>Germany N=100</th>
<th>France N=100</th>
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<tr>
<td>Very</td>
<td>49%</td>
<td>41%</td>
<td>33%</td>
</tr>
</tbody>
</table>

Avg. 73%

Based on the information provided, please rate your overall level of interest in Therapy X.

**Over 90% Satisfaction Rate Among US Study Participants**
(US Pivotal Trial Survey, 2015)

Overall, how satisfied are you with your experience with the AspireAssist?

- Very Satisfied (69%)
- Somewhat satisfied (23%)
- Neutral (3%)
- Somewhat dissatisfied (2%)
- Very dissatisfied (3%)
- No response (1.6%)

Yes (98%)

I am glad I decided to participate in the PATHWAY study.

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Multiple European Studies Ongoing

Ongoing studies across Europe continue to support excellent weight loss results and safety profile

Swedish Post-Market Study
- 25 Subjects
- BMI 35-49

6-Month Results Published in *Endoscopy* 2015:
41% EWL, 36 pounds

Pan-European Post-Market Registry
- Enrolling 50 Subjects
- Spain, Austria, Czech, Italy, Belgium, Greece, UK
- BMI 35-65

Germany & Austria Post-Market Study
- Enrolling 30 Subjects
- BMI 35-65

Head-to-Head vs Gastric Bypass
- Enrolling 100 Subjects
- Sweden
- BMI 35-49

Super-Obese
- Enrolling 30 Subjects
- Czech Republic, Spain, Belgium, France
- BMI 59-79 to date
171 SUBJECT TRIAL ACROSS 10 LEADING INSTITUTIONS

• Body Mass Index (BMI) 35 – 55
• Failed previous weight loss attempts

2:1 RANDOMIZATION

• 111 AspireAssist, 60 Lifestyle Therapy

PRIMARY ENDPOINTS

• Mean percent Excess Weight Loss (EWL) >10% over control at 52 weeks
• At least 50% “Responder Rate” at 52-weeks (defined as 25% EWL)

Institutions

Boston Medical Center
Brigham & Women’s Hospital
Weill Cornell Medical College
St. Mary Medical Center
University of Pennsylvania
Howard University
Northwestern University
Mayo Clinic
Washington University
VA Center/ UC San Diego

Data locked in June 2015

BOTH PRIMARY ENDPOINTS WERE MET; TRIAL SUCCESSFUL
Entering Final Stage of FDA Approval Process

- Complete Enrollment: June 2014
- File Pre-Submission: March 2014
- 52-Week Endpoints: June 2015
- Submit Pre-Market Approval Application: July 2015
- FDA Approval

Anticipated H1 2016

Expected U.S. launch in early-to-mid 2016