ASPIRE assist®

An Intelligent, Endoscopic Solution for Obesity

Introducing the first and only

LONG-TERM & REVERSIBLE

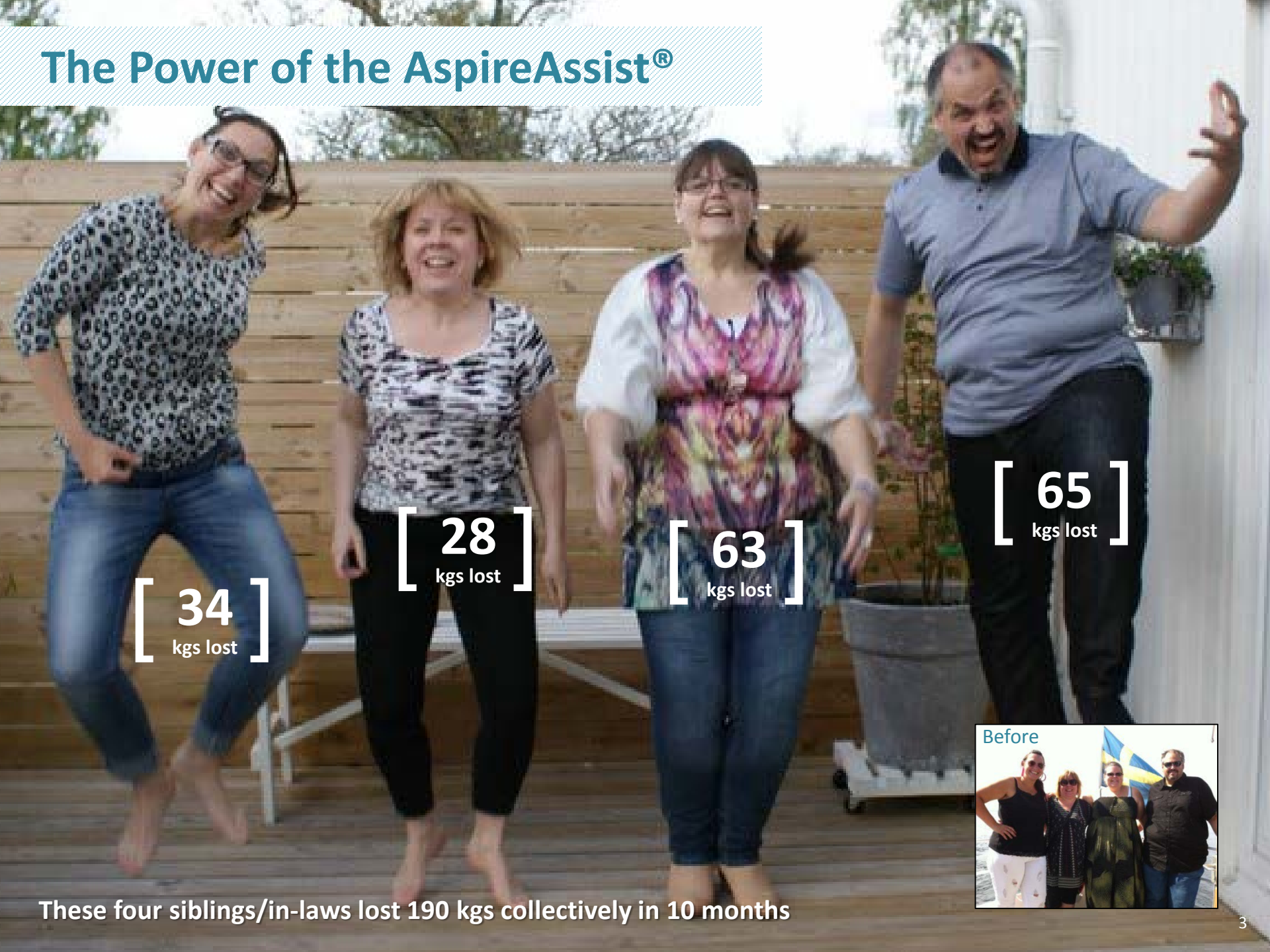
endoscopic obesity solution, with the

power to address

obese and super-obese patients.

ASPIRE

The Power of the AspireAssist®



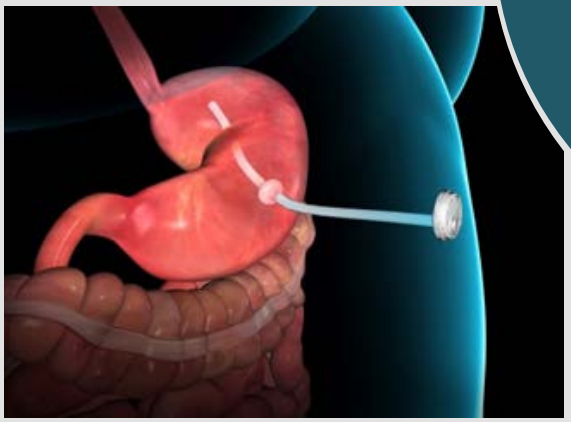
These four siblings/in-laws lost 190 kgs collectively in 10 months

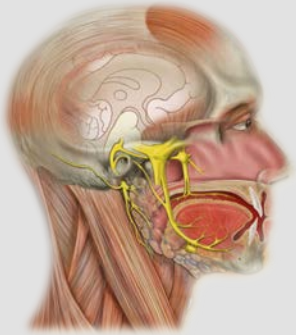
AspireAssist: Dual Mechanism for Long-Term Results

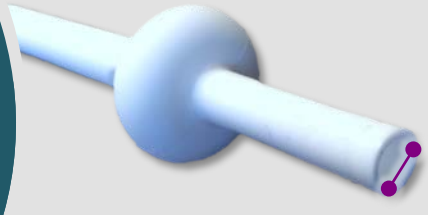
30 Percent

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

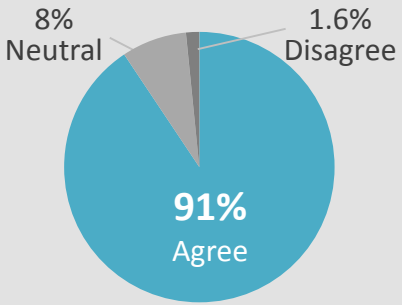
Removes up to 30% of calories, directly into toilet

Discreet port “button” when not in use

Patients aspirate after each main meal, three times per day.

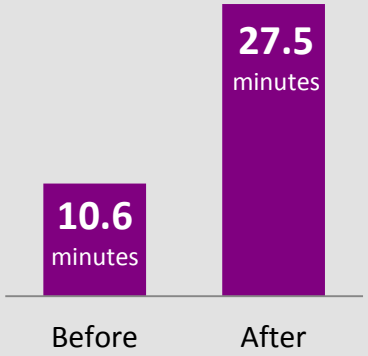
Secondary Mechanism: Intake Modulation

Increased Chewing
(May/June 2015)

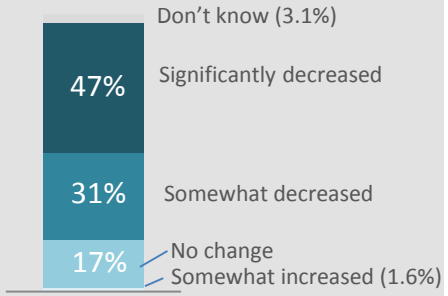


I chew my food more thoroughly since beginning therapy with the AspireAssist.

Increased Meal Consumption Time
(May/June 2015)



Reduced Calorie Consumption
(May/June 2015)



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.

Chewing and Calorie Change data from US. Pivotal Trial Survey, 2015. Meal consumption time data from 2015 OUS Patient Survey (not recorded in US Pivotal Trial Survey).

Lifestyle Counseling Reinforces Healthy Habits

Drinking Water

Nutritious Choices

Exercise

LIFESTYLE CHANGE IS
PARAMOUNT
TO ASPIREASSIST® THERAPY

Support Community

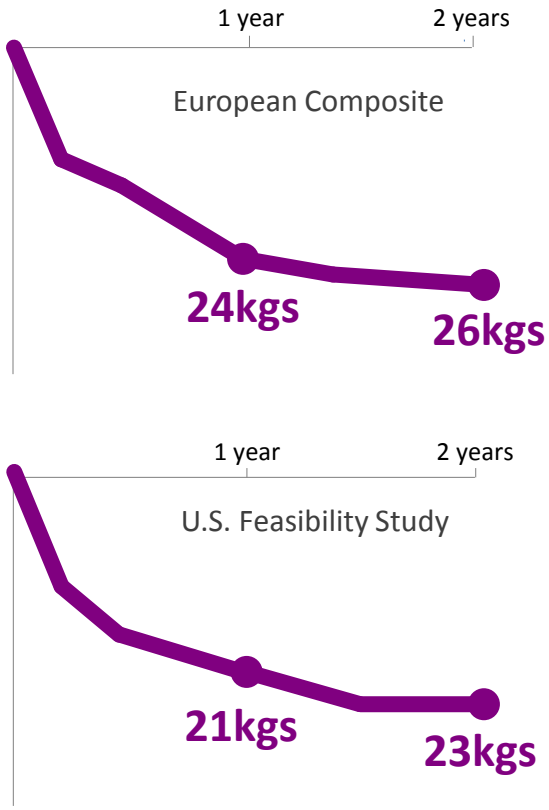
Mindfulness

Limited Snacking

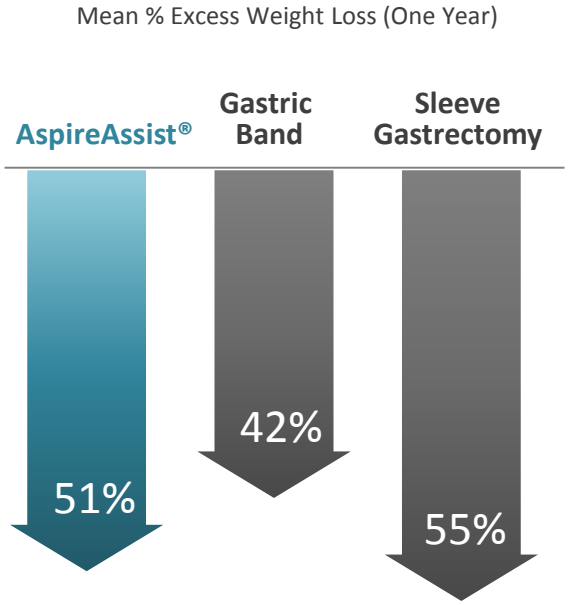
All patients receive lifestyle counseling with AspireAssist therapy, typically about 10 sessions in first year

Proven Clinical Results

Mean 2-Year Weight Loss



Comparable Results to Bariatric Surgery…



…with the safety profile for even high-BMI patients

Source: US Feasibility Study: Shelby Sullivan et al, Washington University St. Louis. See Gastroenterology 2013; 145:1245–1252. n=10 at 1 year, n=7 at 2 years.
European composite data collected from Sweden, Spain, Czech republic, Belgium. N=36 at 1 year, N=16 at 2 years (ongoing study).

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

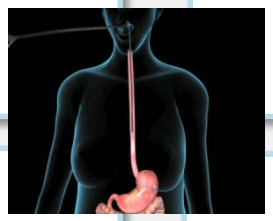
STANDARD PEG PROCEDURE REQUIRES NO ADDITIONAL TRAINING

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 CONCIOUS SEDATION
General anesthesia is typically not necessary



OUTPATIENT
Patients return home within 2 hours

HIGH PROCEDURE SUCCESS
Adequate transillumination in >99% of patients

Long-term and Reversible. Best of Both Worlds.

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

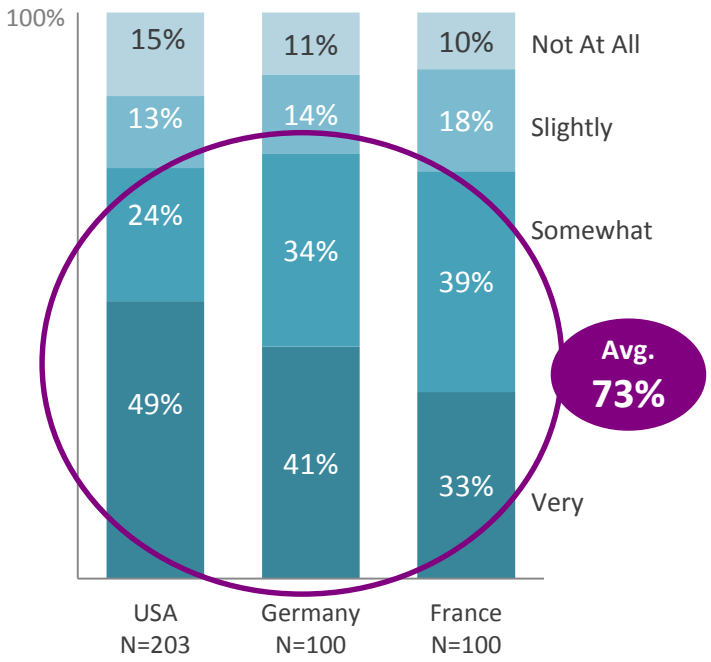
EASILY REVERSIBLE

Tube can be removed at any time in a simple 10-minute endoscopy

Patient Acceptability

Strong Patient Interest in AspireAssist

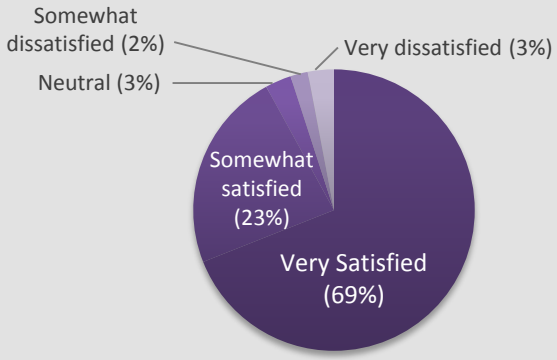
(International Market Research 2014)



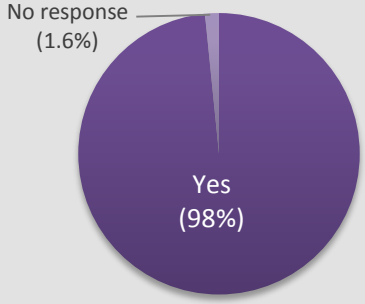
Based on the information provided, please rate your overall level of interest in Therapy X.

Over 90% Satisfaction Rate Among US Study Participants

(US Pivotal Trial Survey, 2015)



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



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

Multiple European Studies Ongoing

ASPIRE

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

PATHWAY U.S. Pivotal Trial Design

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)

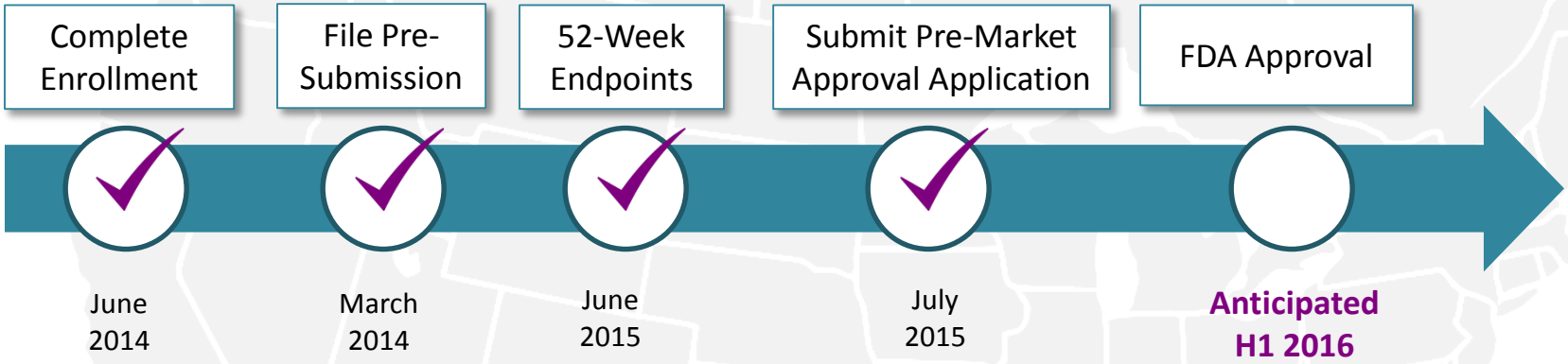
Institutions

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



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


ASPIRE
assist®