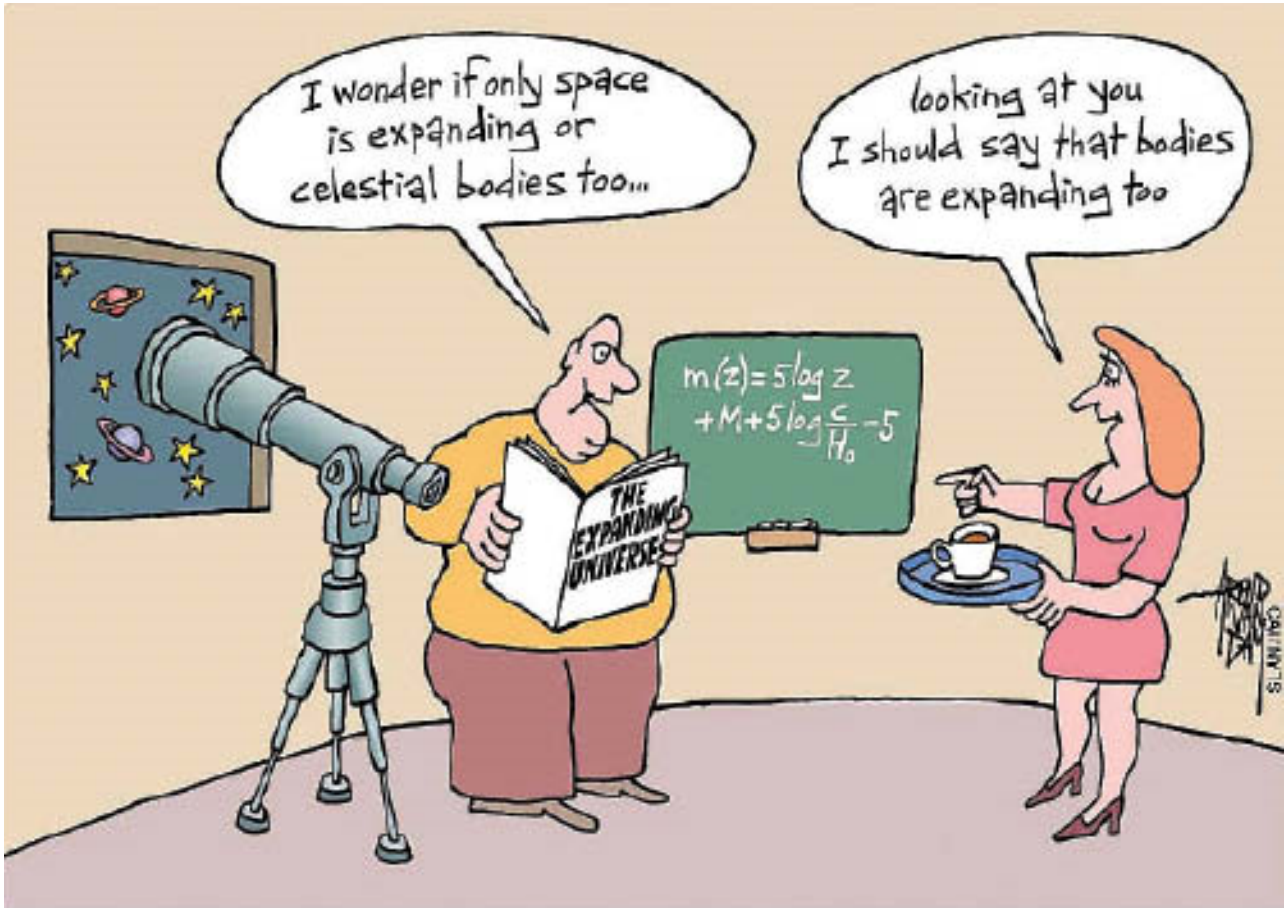
Obesity Devices

Jeffrey Cooper, M.S., D.V.M.
Chief, Gastroenterology Devices Branch
Division of Reproductive, Gastro-Renal and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration

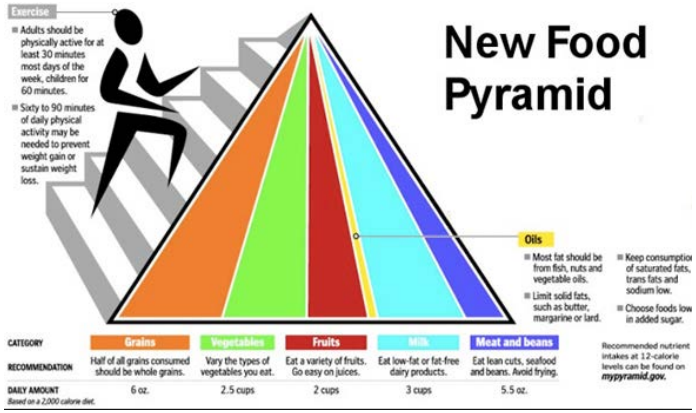
There is a problem

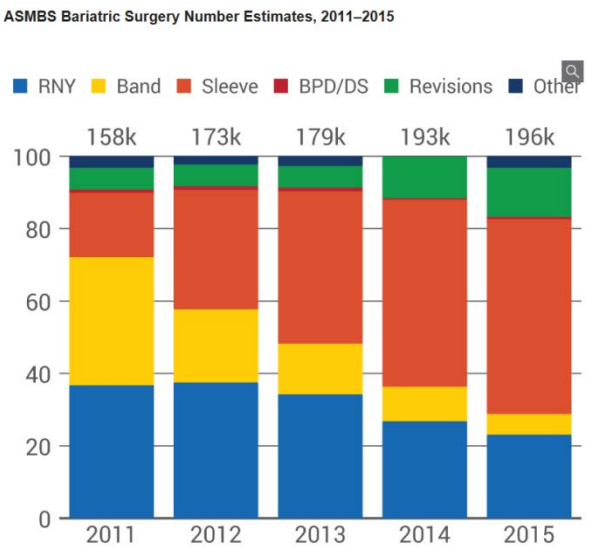
https://fattylane.wordpress.com/2011/09/27/thats-my-parking-space/

The Obesity Space

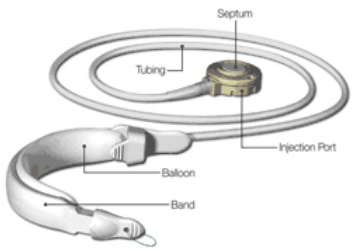


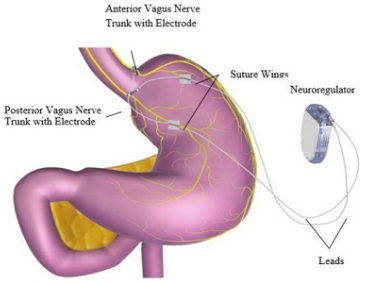
Treatment Options

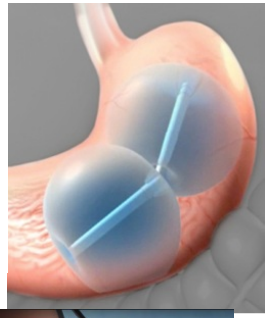


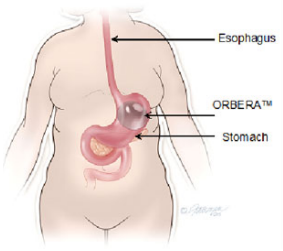


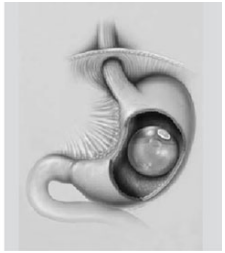
American Society for Metabolic and Bariatric Surgery

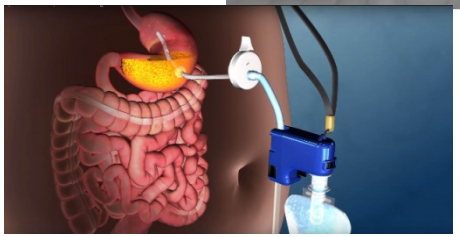












Types of Devices

- Restrictive (endoscopic suturing/stapling devices)
- Neuromodulation (vagus nerve stimulator);
- Space occupying (intragastric balloons, swallowable capsules)
- Aspiration therapy
- Bypass (endoscopic sleeves/magnetic anastomosis device)
- Flow control
- Emerging Devices

How Does FDA Regulate Devices?

	Class I	Class II	Class III
Risk level	Low	Moderate	High
Sufficient information for controls?	General	General & Special	Insufficient
Premarket review?	Mostly exempt	510(k) De novo	PMA
Examples	Tongue depressor, stethoscope	Endoscopes, infusion pumps	Cardiac ablation catheters, most weight loss devices
Predicate	N/A	Yes [510(k)]	No

Device Ideas

- EnteroMedics Inc. MAESTRO System Implantable neuromodulation device
- Apollo Endosurgery Inc. Orbera Intragastric Balloon System
- Aspire Bariatrics Inc.AspireAssist Aspiration Therapy System
- Allurion Technologies Inc. Elipse Intragastric
- BAROnova Inc.BAROnova TransPyloric Shuttle
- BKFW Full Sense Device
- Endobetix Ltd.Bile Diversion
- EndoSphere Inc.SatiSphere System
- Fulfillium Inc.N/AIntragastric balloon
- Gelesis Inc.Gelesis100
- GI Dynamics Inc.EndoBarrier Liner
- GI WindowsIncisionless Anastomosis System
- Helioscopie Medical ImplantsHeliosphere BAG Intragastic Air Balloon
- MelCap SystemsCombined swallowable intragastric balloon/neuromodulation device
- Obalon Therapeutics Inc.Obalon
- PlenSatDigestible Intragastric Balloon
- Scientific Intake Ltd. SmartByte Device
- Spatz FGIA Inc.Spatz3 Adjustable Balloon System
- SynerZ Medical Inc.Aegis
- Tulip Medical LtdIntragastric balloon
- USGI Medical Inc.Incisionless Operating Platform
- ValenTx Inc.ValenTx Bypass System

Medtech Insight | Pharma Intelligence, 2016 as outlined in Obesity 2016: Minimally Invasive Bariatric Devices Gaining Steam, July 20, 2016 analysis by Anne Staylor ---- https://medtech.pharmamedtechbi.com/MT103608/Obesity-2016-Minimally-Invasive-Bariatric-Devices-Gaining-Steam

FDA has Approved Six of these Devices

- Lap-Band Gastric Banding System
- Realize Gastric Band
- Maestro Rechargeable System
- ReShape Integrated Dual Balloon System
- ORBERA Intragastric Balloon System
- AspireAssist device

Lap-Band Gastric Banding System

- The Lap-Band System is a surgically implanted device that helps adults who are at least 18 years old eat less and lose weight. The Lap-Band consists of a silicone band, tubing, and an access port. The inner surface of the silicone band is inflatable and is connected by the tubing to the access port.

- The band limits the amount of food that can be eaten at one time and increases the time it takes for food to be digested, helping people to eat less.

- The FDA approved the Lap-Band System for use in obese patients with a Body Mass Index (BMI)of at least 40. It is also approved for patients with a BMI of 30-40 with one or more obesity-related medical conditions, such as high blood pressure, heart disease, diabetes or sleep apnea. This device is indicated for use only in adult patients who have failed non-surgical weight-loss alternatives, such as supervised diet, exercise and behavior modification programs.

Realize Gastric Band

- The Realize Band is a surgically implanted device used to help adults (18 years of age or older) lose weight. The Realize Band consists of a silicone band, tubing, and an injection port.

- The band helps a person eat less by limiting the amount of food that can be eaten at one time and increasing the time it takes for food to be digested.

- The FDA approved the Realize Band for patients who are morbidly obese, with a BMI of at least 40. It is also approved for patients with a BMI of at least 35 with one or more obesity-related medical conditions. The Band is indicated for use only in adult patients who have failed non-surgical weight-loss alternatives, such as supervised diet, exercise and behavior modification programs.

Maestro Rechargeable System

- The Maestro Rechargeable System is an electrical stimulator that is surgically implanted into the abdomen to block nerve activity between the brain and the stomach. It consists of a rechargeable electrical pulse generator, wire leads and electrodes and is used to help people who are at least 18 years old lose weight.

- The Maestro System works by sending intermittent electrical pulses to the vagus nerve, which is involved in regulating stomach emptying and signaling to the brain that the stomach feels empty or full. External controllers allow the patient to charge the device and allow health care professionals to adjust the device's settings in order to provide optimal therapy with minimal side effects. Although it is known that the electric stimulation blocks nerve activity between the brain and the stomach, the specific mechanisms for weight loss due to use of the device are unknown.

- The FDA approved the Maestro Rechargeable System for use in obese patients who have failed at least one supervised weight management program within the past five years and who have either: a Body Mass Index (BMI) of 40 to 45, or a BMI of 35 to 39.9 and one or more obesity-related conditions, such as diabetes, high blood pressure, and sleep apnea.

- Average Total Body Weight Loss (TBWL) = 9.2%

ReShape Integrated Dual Balloon System (Reshape Dual Balloon)

- The ReShape Integrated Dual Balloon System (Reshape Dual Balloon) is a weight-loss system of gastric balloons that occupy space in the stomach. The system consists of two attached balloons that are filled and sealed separately. The balloons are placed into the stomach through the mouth using a minimally invasive endoscopic procedure while the patient is under mild sedation. Once in place, the balloons are filled with about 2 cups of salt water (saline) and a blue dye (methylene blue). If a balloon breaks, blue dye will appear in the patient's urine. When it is time to remove the balloons, they are first deflated then removed using another endoscopic procedure.

- The ReShape Dual Balloon takes up space in the stomach to help patients lose weight. The system is temporary and should be removed after 6 months.

- The device is used in adult obese patients who have a Body Mass Index (BMI) of 30-40 kg/m^2 who have been unable to lose weight through diet and exercise. Patients must also have one or more obesity-related conditions such as diabetes, high blood pressure, or high cholesterol. Reshape Dual Balloon is intended to be used while a patient participates in a diet and exercise plan supervised by a health care provider.

- Average TBWL= 6.8%

ORBERA Intragastric Balloon System

- The ORBERA Intragastric Balloon System is a weight-loss system that uses a gastric balloon that occupies space in the stomach. The balloon is placed into the stomach through the mouth, using a minimally invasive endoscopic procedure, while the patient is under mild sedation. Once in place, the balloon is filled with salt water (saline) so that it expands into a spherical shape. The balloon can be filled with different amounts of saline (from 400 to 700 cc) to best match the patient's body structure.

- The ORBERA Intragastric Balloon System takes up space in the stomach to help patients lose weight. The system is temporary and should be removed after 6 months.

- The device is used in obese adult patients who have a Body Mass Index (BMI) of 30-40 kg/m^2 who have been unable to lose weight through diet and exercise. It is intended to be used while a patient participates in a diet and exercise plan supervised by a health care provider.

- Average TBWL= 10.2%

AspireAssist

- The Aspire Assist Device uses a surgically-placed tube to drain a portion of the stomach contents after every meal.
- The AspireAssist works by reducing the calories absorbed by the body.
- The Aspire Assist Device is intended to assist in weight loss in patients aged 22 and older who are obese, with a body mass index (BMI) of 35 to 55, and who have failed to achieve and maintain weight loss through non-surgical weight-loss therapy.
- Average TBWL=12.1%

How to Evaluate all of these Devices

- We evaluate obesity devices with benefit and risk in mind.
- Effectiveness parameters are a key part of the data needed.
- Each device may have different adverse event data that needs to be collected. A neurostimulator may need data on adverse shocking, while a balloon may need data on rates of ulcers.
- When developing a new Real World Data source, such as a registry, consultation with FDA and other stakeholders is recommended to ensure that relevance and reliability are addressed in the initial design.

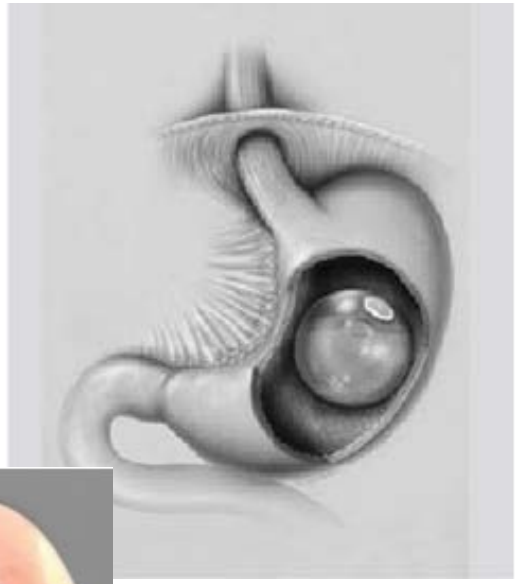
Thank You!

Jeffrey.Cooper@fda.hhs.gov
(301) 796-6517
Chief, Gastroenterology Devices Branch

- EnteroMedics Inc. MAESTRO System Implantable neuromodulation device that intermittently blocks the vagus nerve (VBLOC Therapy) to decrease hunger and induce satiety
- Apollo Endosurgery Inc. Orbera Intragastric Balloon System is a Spherical silicone balloon endoscopically placed into the stomach under mild sedation, and filled with saline/methylene blue dye (from 400 to 700 cc). Endoscopically removed after 6 months.
- Aspire Bariatrics Inc.AspireAssist Aspiration Therapy System is endoscopically implanted tube allowing patients to aspirate a portion of their stomach contents after each meal through a port at the skin surface.
- Allurion Technologies Inc. Elipse Intragastric Balloon is a Swallowable capsule/balloon with thin delivery catheter for filling. Once in the stomach, the capsule is filled with 550 ml of fluid, the catheter is detached, the fill valve seals shut, and the catheter is removed. The valve automatically opens at four months, allowing the balloon to empty and pass through the GI tract. Does not require endoscopic placement or removal.
- BAROnova Inc.BAROnova TransPyloric ShuttleEndoscopically delivered device designed to self-position across the pylorus and create an intermittent obstruction to outflow that may result in delayed gastric emptying.
- BKFW Full Sense Device is Endoscopically placed temporary implant that applies physical pressure to the patient's distal esophagus and proximal stomach to induce satiety even without the presence of food
- Endobetix Ltd.Bile Diversion Device is Endoscopically placed implant that diverts bile and pancreatic secretions from the duodenum to the jejunum.
- EndoSphere Inc.SatiSphere System is a small, C-shaped nitinol wire that incorporates five soft, porous, braided sphere structures along its length; services to hold food within the duodenum temporarily (also serves a flow control function).

Medtech Insight | Pharma Intelligence, 2016 as quoted in Obesity 2016: Minimally Invasive Bariatric Devices Gaining Steam, July 20, 2016 analysis by Anne Staylor

Intragastric Balloon Design Comparison

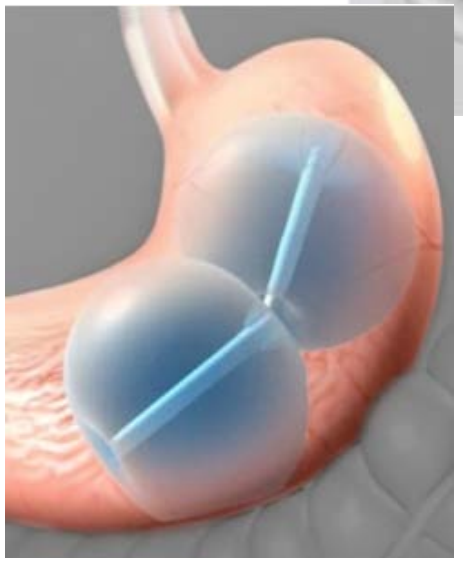


ORBERA™ System

- Single silicone balloon
- Endoscopic placement
- Filled with saline
- Range fill 400 - 700 cc

Reshape System

- Two silicone balloons filled and sealed separately
- Endoscopic placement
- Filled with saline and methylene blue dye
- Range fill 375 - 450 cc per balloon



Indications For Use Comparison

The ***ReShape*** **Integrated Dual Balloon System** is indicated for weight reduction when used in conjunction with diet and exercise, in obese patients with a Body Mass Index (BMI) of 30 – 40 kg/m^2 and one or more obesity-related comorbid conditions. It is indicated for use in adult patients who have failed weight reduction with diet and exercise alone.

The **ORBERA™ Intragastric Balloon System** is indicated for use as an adjunct to weight reduction for adults with obesity with Body Mass Index (BMI) of ≥ 30 and ≤ 40 kg/m^2 and is to be used in conjunction with a long-term supervised diet and behavior modification program designed to increase the possibility of significant long-term weight loss and maintenance of that weight loss. ORBERA™ is indicated for adult patients who have failed more conservative weight reduction alternatives, such as supervised diet, exercise and behavior modification programs. The maximum placement period for ORBERA™ is 6 months.