Devices for endoluminal bariatric procedures

1. INTRA-GASTRIC BALLOONS

| BioEnterics® BIB® System | NAME of the products  
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BioEnterics® BIB® System</td>
</tr>
<tr>
<td>CODES</td>
<td></td>
</tr>
<tr>
<td>MANUFACTURER</td>
<td>ALLERGAN, INC.</td>
</tr>
<tr>
<td></td>
<td>2525 Dupont Drive - Irvine, California - USA</td>
</tr>
<tr>
<td>DESCRIPTION</td>
<td>Fluid-filled intragastric balloon approved for 6-month implantation.</td>
</tr>
<tr>
<td>FEATURES</td>
<td>The BIB® System or BioEnterics® Intragastric Balloon System is a soft, expandable, latex-free silicone balloon that is placed inside the stomach via a camera that enters through the mouth and into the stomach. Once inserted in the stomach, the empty balloon is filled with blue-marked isotonic saline. It has a spherical shape and smooth surface, and a radiopaque marker to allow proper follow-up of the device. Recommended saline volumes are 400-500 cc, inserted through a self sealing valve.</td>
</tr>
<tr>
<td>UNIQUE DIFFERENCES</td>
<td>(to other instruments)</td>
</tr>
<tr>
<td>FURTHER READING:</td>
<td><a href="http://www.allergan.com">http://www.allergan.com</a></td>
</tr>
</tbody>
</table>
Spatz adjustable balloon

PICTURES

Spatz3 Adjustable Balloon System

Insertion facilitator

Easy Grasp Valve

NAME of the products

Spatz3 Adjustable Balloon System

CODES

MANUFACTURER
Spatz FGIA, Inc
15 Cuttermill Road, # 147 - Great Neck, NY 11021 – USA

DESCRIPTION
Fluid-filled, adjustable, intragastric balloon approved for 12-month implantation.

FEATURES
The Spatz™ Adjustable Balloon System is a fluid-filled balloon with an attached anchor and adjustability valve. The saline-filled gastric balloon sits in the stomach cavity and is intended to decrease appetite by occupying about one third of the stomach volume, as well as by slowing down stomach emptying. A retractable/stretchable silicone inflation tube allows the balloon to have its volume adjusted after initial insertion, while the balloon remains in the stomach. Early intolerance can be successfully treated with fluid removal from the balloon. Weight loss plateau can be successfully treated with addition of fluid to the balloon.

CE Marked; not approved by the FDA for use in the United States.

UNIQUE DIFFERENCES (to other instruments)

- volume adjustability
- Approved for one year implantation

FURTHER READING:
http://www.spatzmedical.com
**Obalon Gastric Balloon System**

<table>
<thead>
<tr>
<th>PICTURES</th>
<th>NAME of the products</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Swallowable capsule" /></td>
<td>Obalon Balloon</td>
</tr>
<tr>
<td><img src="image2.png" alt="Obalon" /></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CODES</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>MANUFACTURER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obalon Therapeutics</td>
</tr>
</tbody>
</table>

5421 Avenida Encinas, Suite F - Carlsbad, CA 92008-4410 - USA

<table>
<thead>
<tr>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Air-filled, swallowable, intragastric balloon approved for 12 weeks implantation.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FEATURES</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Obalon system features three elements: a swallowable capsule with the balloon folded inside; a catheter attached to the capsule for balloon inflation and easy catheter removal; a 250 cc Balloon filled with gas that resides in the gastric fundus.</td>
</tr>
<tr>
<td>The balloon technology utilizes a capsule that contains the balloon inside. The capsule is attached to a tiny tube that allows inflation. The patient drink a cup of water and swallows the capsule with the tube attached. Once the capsule reaches your stomach, it opens up and releases the balloon. The balloon placement is conformed by x-ray and then it is inflated with gas. After the balloon is inflated, the tube is released.</td>
</tr>
<tr>
<td>A fully inflated single balloon is a sphere with a volume of 250cc, weighing less than 6 grams. Based on patient's weight loss progress, up to 3 balloons can be placed over the 12-week period. The total amount of volume with 2 balloons is 500cc, and 3 balloons is 750cc.</td>
</tr>
<tr>
<td>The balloon(s) is removed by endoscopic procedure.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>UNIQUE DIFFERENCES (to other instruments)</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Swallowable balloon</td>
</tr>
<tr>
<td>- Approved for up to three balloons implantation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FURTHER READING:</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="http://www.obalon.com">http://www.obalon.com</a></td>
</tr>
</tbody>
</table>
## Heliosphere BAG

### PICTURES

<table>
<thead>
<tr>
<th>Heliosphere BAG</th>
<th>Heliosphere BAG-EXTRACT</th>
</tr>
</thead>
</table>

### NAME of the products
- Heliosphere BAG
- Heliosphere BAG PRE-OP
- Heliosphere Bag Extract

### CODES

### MANUFACTURER

**HELIOSCOPIE**
Rue des Frères Lumières- 38200 VIENNE - France

### DESCRIPTION
Air-filled intragastric balloon approved for 6-month implantation.

### FEATURES
- The Heliosphere BAG balloon is a 550 cm³ balloon, 10 cm in diameter. It is air-filled (600 cc) and weight is less than 30 grams.
- The bag has a kit for implantation connected to the bag, while a separate kit for removal is provided.
- The bag is approved for a 6-month implantation.

LNE/G-Med CE marking

### UNIQUE DIFFERENCES (to other instruments)

- Air-filled

### FURTHER READING:

http://www.helioscopie.fr
PICTURES

Pre-implanted kit with protector tube

NAME of the products
EndBall

CODES
END-T70
END-90
END-T110

MANUFACTURER
ENDALIS
Parc de Sacuny - 313B av Marcel Mérieux
69530 BRIGNAIAS, France

DESCRIPTION
Liquid and air-filled intragastric balloon approved for 6-month implantation.

FEATURES
Latex-free silicone balloon with radio-opaque valve.
Maximum volume: 500 ml for END-T70 (300 cm³ liquid + 2 60 ml syringe of air), 600 ml for END-T90 (400 cm³ liquid + 2 60 ml syringe of air) and 800 ml for END-T110 (500 cm³ liquid + 3 60 ml syringe of air)

CE marked (class IIb)

UNIQUE DIFFERENCES (to other instruments)

FURTHER READING:
http://www.endalis.com/index_gb.html
view in the stomach

ACCESSORIES

Universal biconical connector

Extraction hooks

Hollow drainage needles
<table>
<thead>
<tr>
<th>NAME of the products</th>
<th>ENDGAST-ATIIP</th>
</tr>
</thead>
<tbody>
<tr>
<td>DESCRIPTION</td>
<td>ADJUSTABLE TOTALLY IMPLANTABLE INTRA GASTRIC PROSTHESIS - ATIIP</td>
</tr>
<tr>
<td>CODES</td>
<td>ENDO-25D</td>
</tr>
<tr>
<td>MANUFACTURER</td>
<td>DISTRICLASS MEDICAL S.A. / COFRAMED</td>
</tr>
<tr>
<td>ADDRESS</td>
<td>BP 14 110, Allée Louis Lépine - ZA Chapotin Sud 69970 CHAPONNAY – France</td>
</tr>
<tr>
<td>DESCRIPTION</td>
<td>Air-filled intragastric balloon approved for long-lasting implantation.</td>
</tr>
<tr>
<td>FEATURES</td>
<td>Air-filled oval polyurethane prosthesis (210-300 ml) inserted with a combined endoscopic-surgical procedure in the gastric corpus-fundus area using a method similar to the percutaneous endoscopic gastrostomy technique and connected to a subcutaneous completely implantable system (fixing the stomach to the abdominal wall) which avoids dislocations and allows adjustment of the volume of the balloon.</td>
</tr>
<tr>
<td>UNIQUE DIFFERENCES</td>
<td>CE marked</td>
</tr>
</tbody>
</table>

 UNIQUE DIFFERENCES (to other instruments) |

 - Implantable system
 - Balloon connected to a subcutaneous port

FURTHER READING:
Implantation technique

1. Determine the abdominal entry point
2. Skin incision at puncture point
3. Puncture leaving only the cannula in place
4. Insert cannula through the incision
5. Attach the prosthesis to the guide wire
6. Pull the catheter out of the stomach wall
7. Tunnel the catheter to the implantable port pocket
8. Connect the implantable port

With implantation technique proposed by Dr. Giorgio GAGGIOOTTE
**Semi-stationary Antral Balloon** (JP Industria Farmaceutica, Ribeirao Preto, Brazil)  

Pear-shaped device, filled with saline (150-180 ml), and with a 30 cm silicone duodenal stem for anchoring in the antrum with its conical pole oriented to the pylorus and a 7-g metallic counterweight at tip. Its theoretical mechanism is the intermittent occlusion of the pyloric opening, prolonging gastric emptying and stimulating antroduodenal satiety receptors.

**Ullorex® Oral Intragastric Balloon** (Phagia Technologies, Inc., USA)  

The Ullorex balloon attempts to completely remove the need for endoscopic placement and removal. It consists of a large capsule that is injected with citric acid and swallowed within a 4-minute period. The injected acid reacts with sodium bicarbonate and slowly inflates the balloon with carbon dioxide to a volume of 300 cm³. The balloon has a plug which is eventually degraded by stomach acid over 25 to 30 days, thus allowing the balloon to deflate and pass through the digestive tract (Martin et al 2007).

**Silimed Gastric Balloon** (Silimed Brazil) – fluid filled balloon  
http://www.silimed.com.br  

The Silimed Company (Silimed Brazil) has designed a spherical transparent balloon made of silicone coated with a self-sealing valve that is filled with 650 ml of saline. It is characterized by being advanced by scope traction under direct visualization, rolled up inside a thin silicone sheath anchored to the tip of the endoscope with a snare. It’s removed as an entire system held in an overtube.
2. RESTRICTIVE PROCEDURES (transoral gastric volume reduction)

**Transoral gastroplasty (TOGA)**

<table>
<thead>
<tr>
<th>PICTURES</th>
<th>NAME of the products</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TOGA System</td>
</tr>
</tbody>
</table>

**CODES**

**MANUFACTURER**

Satiety Inc, Palo Alto, CA

**DESCRIPTION**

Endoscopic full-thickness stapling device that allows exclusion of much of the stomach by creating a narrow gastric sleeve.

**FEATURES**

The transoral gastroplasty or TOGA® system consists of a set of flexible stapling devices that are utilised to create a restrictive gastric pouch or sleeve that induces the feeling of satiety after a small meal.

**UNIQUE DIFFERENCES** (to other instruments)

**FURTHER READING:**

The company developping TOGA closed down and sold its assets end of 2010.
**Transoral Gastric Volume Reduction (TRIM procedure)**

<table>
<thead>
<tr>
<th>NAME of the products</th>
</tr>
</thead>
<tbody>
<tr>
<td>EndoCinch</td>
</tr>
<tr>
<td>Restore Suturing System</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CODES</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>MANUFACTURER</th>
</tr>
</thead>
<tbody>
<tr>
<td>C. R. Bard, Inc.</td>
</tr>
<tr>
<td>730 Central Avenue - Murray Hill, NJ 07974 USA</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endoscopic suturing device.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FEATURES</th>
</tr>
</thead>
<tbody>
<tr>
<td>EndoCinch, originally developed as an endoscopic treatment for GERD, is a suturing device that is mounted on the tip of the endoscope. This overtube-based device uses a suction chamber to capture the gastric wall and creates pleats using tagged sutures to reduce gastric volume. The most recent iteration of this device (the Restore Suturing System) allows for the creation of deeper, full-thickness plications and eliminates the need for device withdrawal for suture reloading as was required by its predecessor. In addition to primary obesity therapy (Transoral Gastric Volume Reduction or TRIM procedure) it can be used for revision of dilated gastrojejunal anastomoses in gastric bypass.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>UNIQUE DIFFERENCES (to other instruments)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>FURTHER READING:</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="http://www.crbard.com">http://www.crbard.com</a></td>
</tr>
</tbody>
</table>

---

**PICTURES**

Restore Suturing System uses a suction capsule placed on the end of a standard endoscope. Suction is applied to capsule using tubing attached to outside of endoscope. Suturing system and suture fastening system are operated through working channel of the endoscope. Multiple gastric plications can be completed with single esophageal intubation and no overtube.

Capsule applied to tissue, and suction applied. Needle drives suture and suture tag through muscular wall of stomach and deposits tag in end of capsule.
Tag and suture are retrieved from end of capsule by activating plunger on device. Capsule is then positioned for next suture placement.

After the desired number of bites have been taken, the suturing device is removed from the working channel over the sutures, and the suture fastening device is passed down the working channel over the sutures. The tissue is approximated by pulling the free ends of the sutures outside the endoscope.

Once the plication has been approximated, the fastener is deployed, and the suture cut with activation of the fastening device. Another suturing device is then placed down the working channel, and the steps are repeated.
Endoluminal gastroplasty
Transoral Endoscopic Restrictive Implant System (TERIS)

PICTURES

NAME of the products
TERIS™ (Trans-oral Endoscopic Restrictive Implant System)

CODES

MANUFACTURER
BAROSENSE, INC.
Redwood City, CA

DESCRIPTION
Endoscopic device designed to implant a prosthetic diaphragm in the gastric cardia via anchors to stapled plications.

FEATURES

Limited by USA law to investigational use.

UNIQUE DIFFERENCES (to other instruments)

FURTHER READING:
http://www.barosense.com/
StomaphyX Delivery System

EndoGastric Solutions, INC.
Redmond, WA, USA

The StomaphyX device is a single-use endoluminal device for ligasure-based creation of plications in the gastric pouch.

http://www.endogastricsolutions.com/

Hourglass Technology (HourGlass Technologies)
3. MALABSORPTIVE PROCEDURES

EndobARRIER Gastrointestinal Liner

NAME of the products
EndobARRIER Liner

CODES

MANUFACTURER
GI DYNAMICS, Inc.
1 Maguire Road, Lexington MA 02421 – USA

DESCRIPTION
Endoluminal malabsorptive device designed to create an endoscopic duodenal-jejunal by-pass.

FEATURES
GI Dynamics’ EndoBarrier® Gastrointestinal Liner System is used for the treatment of type 2 diabetes and/or obesity. It is provided sterile and consists of a gastrointestinal liner (anchor and liner), preloaded in a catheter that delivers the liner to the proximal intestine. The product is sterilized using ethylene oxide. The gastrointestinal liner is removed using the EndoBarrier Gastrointestinal Liner Retrieval System, consisting of a Grasper and Retrieval Hood, which are compatible with standard gastroscopes. The Retrieval System may be supplied either sterile or non-sterile.

The EndoBarrier Liner has a nitinol anchor, an impermeable, fluoropolymer liner with a proximal radiopaque marker and two retrieval drawstrings.

The anchor attaches the gastrointestinal liner to the wall of the bulbous duodenum, proximal to the ampulla of vater. The anchor provides a seal to ensure that chyme passes inside the Liner, and bars on the circumference of the anchor engage the muscularis for fixation. The EndoBarrier Liner extends 61 cm into the small bowel from the anchor site.

Sterile device for one time use only.

GI Dynamics’ EndoBarrier Gastrointestinal Liner Retrieval System consists of the EndoBarrier Retrieval Grasper and Hoods which are packaged together and used to remove the EndoBarrier Liner. They are available sterile (ethylene oxide) or non-sterile. The Retrieval Hoods are compatible with standard gastroscopes.

CE marked; limited by USA law to investigational use.
**UNIQUE DIFFERENCES** (to other instruments)

It avoids contacts between ingested food and duodeno-jejunal mucosa for a 60 cm-length.

**FURTHER READING:**
http://www.gidynamics.com/endobarrier-overview.php
http://www.endobarrier.com/
<table>
<thead>
<tr>
<th>PICTURES</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="ValenTX" /></td>
</tr>
<tr>
<td><img src="image2.png" alt="Implanted ValenTx" /></td>
</tr>
</tbody>
</table>

**NAME of the products**
ValenTx Endoluminal Bypass

**CODES**

**MANUFACTURER**
ValenTx, Inc
5464 Carpinteria Ave, Suite G
Carpinteria, CA 93013 – USA

**DESCRIPTION**
Endoluminal malabsorptive device designed to create an endoscopic gastric by-pass.

**FEATURES**
The ValenTx endoluminal bypass therapy accomplishes the same changes as the gastric bypass procedure, obtaining these with an implantable endoluminal device.

- It is implantable, removable, and replaceable with a trans-oral approach. It consists on a intraluminal 120 cm length sleeve of gastro-duodenum-jejunal derivation, implanted in the esophagus-gastric junction.

- The ValenTx endoluminal bypass is not FDA approved, not commercially available, and subject to ongoing clinical investigation.

**UNIQUE DIFFERENCES (to other instruments)**

**FURTHER READING:**
http://www.valentx.com
**NAME of the products**  
AspireAssist™ Aspiration Therapy System

**CODES**

**MANUFACTURER**  
Aspire Bariatrics, Inc.  
3200 Horizon Drive, Suite 100  
King of Prussia, PA 19406 – USA

**DESCRIPTION**  
Gastric contents aspiration therapy, intended for long-term use.

**FEATURES**

To begin Aspiration Therapy, a specially designed tube, the A-Tube™, is placed in the stomach. The A-Tube is a thin silicone rubber tube that connects the inside of the stomach directly to a poker-chip sized Skin-Port on the outside of the abdomen. The Skin-Port has a valve that can be opened or closed to control the flow of stomach contents. The patient empties a portion of stomach contents into the toilet after each meal through this tube by connecting a small, handheld device to the Skin-Port. The aspiration process is performed about 20 minutes after the entire meal is consumed and takes 5 to 10 minutes to complete.

The AspireAssist is not approved for sale in the United States and is limited by United States law to investigational use.

**UNIQUE DIFFERENCES** (to other instruments)

**FURTHER READING:**
http://www.aspirebariatrics.com
## 4. GASTRIC NEUROMODULATION-BASED ENDOLUMINAL PROCEDURES

### Full-Sense Device

<table>
<thead>
<tr>
<th>PICTURES</th>
<th>NAME of the products</th>
<th>CODES</th>
<th>MANUFACTURER</th>
<th>DESCRIPTION</th>
<th>FEATURES</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Full-Sense Device" /></td>
<td>Full Sense™ Bariatric Device</td>
<td></td>
<td></td>
<td>Cylindrical stent placed above gastroesophageal junction with a conical component sitting in the cardia.</td>
<td>The Full Sense Device is placed via endoscopy in the distal esophagus and proximal stomach. By applying pressure to this area it causes satiety without the need for the presence of food.</td>
</tr>
<tr>
<td><img src="image2.png" alt="Implanted Full-Sense" /></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>The Full Sense device consists of a conical component which sits in the cardia, and a cylindrical stent that is placed just above the gastroesophageal junction. The two components are attached by a tether that passes through the junction, which causes the conical component to place upwards pressure on the top of the stomach.</td>
</tr>
</tbody>
</table>

**UNIQUE DIFFERENCES** (to other instruments)

**FURTHER READING:**
keuper@legcap.com
http://www.bariatricnews.net/?q=news/11102/new-endoscopic-stent-can-lead-100-ewl
5. SUTURING DEVICES

POSE (Primary Obesity Surgery, Endoluminal) and ROSE (Restorative Obesity Surgery, Endoluminal)

The IOP (USGI Medical, San Clemente, CA) is a multifunctional endoscopic platform that has been applied to primary obesity therapy in a procedure called Primary Obesity Surgery, Endoluminal or POSE. Moreover, the IOP can be used for revision of dilated gastric pouches and dilated gastrojejunal stomas (ROSE).

The Incisionless Operating Platform (IOP) includes the Transport® Endoscopic Access Device - Retroflex, the g-Prox® EZ-33 Endoscopic Grasper, g-Cath™ EZ Delivery Catheter with Snowshoe Suture Anchors™, and the g-Lix™ Tissue Grasper. The Incisionless Operating Platform addresses many of the challenges of endolumenal surgery.

http://www.usgimedical.com

Redo Bypass con OTSClips to reduce the pouch

OverStitch (Apollo Endosurgery, Austin, TX)

The Overstitch device by Apollo Endosurgery is a new and innovative device to revise the gastric bypass. It is an endoscopic suturing device that will tighten the connection between the gastric pouch and the small intestine. The procedure will give the gastric bypass patient the feeling of restriction and a feeling of fullness like they did with their original procedure.