June 15, 2016

Aspire taps into obesity market

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It is one of the more unusual FDA approvals, but the go-ahead for Aspire Bariatrics' AspireAssist weight-loss device shows how desperate healthcare systems are for new options to treat obesity. The device can be best described as a tap that allows patients to jettison part of their stomach contents after eating.

While it is difficult to tease out the relative effects of the various available weight loss devices, AspireAssist seems to compare well with the two recently approved gastric balloons (see table below). But it still falls short of the efficacy seen with gastric bypass surgery.

Gastric bypass can help patients lose 70% of their excess and 28% of their total weight. The AspireAssist, however, is a much less invasive option, meaning it can be used in less severely obese people.

Gastric bypass is approved for those with a BMI of 40 and over, or 35 and over with an obesity-related comorbidity – while AspireAssist is suitable for people with a BMI of 35-55 who have failed to lose weight using traditional methods.

FDA-approved obesity devices

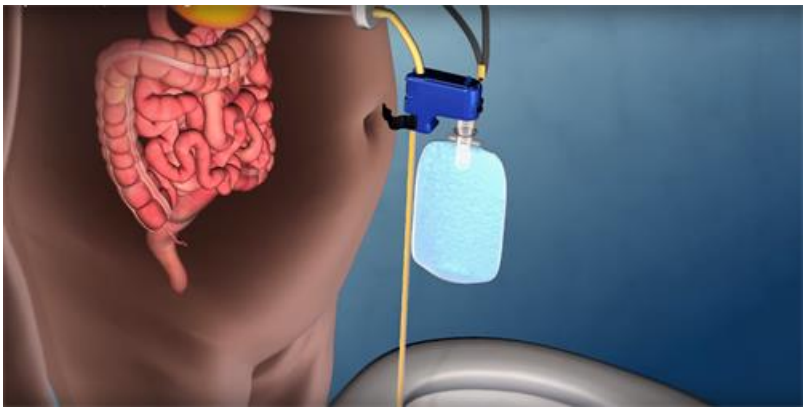
Product	Company	Approval date	Indication	Weight loss in pivotal trial
AspireAssist	Aspire Bariatrics	June 2016	BMI of 35-55	Control-adjusted total weight loss of 8.5% at 12 months
Orbera balloon	Apollo Endosurgery	August 2015	BMI of 30-40	Control-adjusted total weight loss of 6.9% at six months
ReShape Duo ballon	ReShape Medical	July 2015	BMI of 30-40 with comorbidities	Control-adjusted total weight loss of 3.5% at 24 weeks
Maestro neuromodulation system	Enteromedics	January 2015	BMI of 40-45 or 35-40 with comorbidities	Control-adjusted total weight loss of 3.2% at 12 months
Realize gastric band	Ethicon Endo-Surgery (J&J)	September 2007	BMI of 40+ or 30-40 with comorbidities	Mean excess weight loss of 40% at 12 months*
LAP-Band gastric band	Apollo Endosurgery (originally Allergan)	June 2001	BMI of 40+ or 30-40 with comorbidities	Mean excess weight loss of 65%; mean total weight loss of 18% at 12 months*

**No control data available*

Fat tap

The AspireAssist procedure involves a tube being endoscopically inserted into the stomach and attached to a poker chip-sized skin port on the outside of the abdomen.

Around 20-30 minutes after eating patients connect a small handheld device to the port and empty around 30% of the meal into the toilet. This process, which Aspire calls aspiration, takes five to 10 minutes to carry out.



The company says the product provides the “best of both worlds”, being both a long-term solution and easily reversible, unlike gastric surgery.

However, AspireAssist does not spur the same level of weight loss as surgery. The FDA cited data from the 171-patient Pathway trial, which found that patients using the device lost an average of 12.1% of their total body weight after one year, compared with 3.6% in the control group.

An admittedly smaller pilot study found a more impressive 18.6% total weight loss and 49% excess weight loss in the treatment arm at 12 months, versus 5.9% and 14.9% respectively in those who received lifestyle therapy only.

This would make AspireAssist comparable to gastric bands such as Ethicon’s Realize and Apollo’s LAP-Band, and better than gastric balloons, which are also all reversible. Aspire’s device also stacks up well against the drugs approved for obesity.

However, the data are difficult to compare – as well as the usual caution about across-trial analyses, the gastric band studies do not include placebo data (*The skinny on treating obesity – devices vs drugs, July 30, 2015*).

AspireAssist has been dubbed “machine-assisted abdominal vomiting” and “medically assisted bulimia” – but people unable or unwilling to undergo surgery might be up for giving it a try. And with the obesity epidemic showing no signs of abating, the FDA might be amenable to approving other weird and wonderful weight loss devices, too.

Study	Trial ID
Pathway	NCT01766037

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