

Swallowed gastric balloon approved in Europe, but can Elipse eclipse its rivals?



[Elizabeth Cairns](#)

The world's first gastric balloon that does not require an implantation or removal procedure has been granted European CE mark. The Elipse device, made by Allurion Technologies, is swallowed by the patient in its pill-sized collapsed form, and subsequently inflated with liquid via a catheter which is then withdrawn.

Devices to treat obesity have not met with enormous success, largely thanks to the greater weight loss generally seen with drugs. Allurion must hope Elipse's delivery method is a big selling point, as a look at the clinical results seen with these devices puts the balloon distinctly mid-table.

Water balloon

The Elipse device is made of a polymer and is [swallowed with the catheter already attached](#). Once in the stomach the balloon is inflated with 550ml of fluid – the process takes 10 minutes – and the catheter detaches. The device has a valve which opens automatically after around four months, at which point the balloon collapses and can be excreted.

Several gastric balloons are already approved in Europe (see table). The main threats to Elipse are ReShape Medical's ReShape Duo, Apollo Endosurgery's Orbera and Obalon's self-named balloon. The first two must be positioned using an endoscope through the mouth in a 20-30 minute procedure during which the patient is sedated. A second procedure is required to remove these devices six months later.

Obalon's device is closer to the Elipse, as it is swallowed and inflated in much the same way. However it must be removed endoscopically after a treatment period of three months.

Other CE marked devices include gastric bands and a neuromodulation system, EnteroMedics' Maestro.

The gastric bands are by far the most effective, with the Lap-Band, initially developed by Allergan but sold to Apollo Endosurgery in 2013, permitting mean excess weight loss of 65% and mean total weight loss of 18% in its pivotal trial ([The skinny on treating obesity – devices vs drugs, July 30, 2015](#)).

Mid-range

Allurion's device has not so far been shown to permit this degree of slimming. According to interim pilot study data presented at last month's Obesity Week meeting, 34 patients with a body mass index of between 27 and 40kg/m², lost an average of 37% of their excess weight over the four month treatment period.

This puts it ahead of ReShape's balloon but slightly behind Apollo's. In the US approval trial of ReShape Duo, 325 patients with BMI of 30-40 lost 28% of their excess weight, and in Orbera's, 255 patients with BMI of 30-40 had excess weight loss of 40%.

This is a very rough comparison, of course: apart from the usual risks of comparing trials, these studies have different enrolment criteria and treatment periods, and the data on Elipse are much earlier.

It is early days for Allurion – five obesity devices are already on the US market, and Elipse is a few years away from FDA approval – and perhaps its delivery method will give it the edge over other, more effective, devices. But drugs are less invasive still, and tend to result in weight loss as good or better than balloons, though not as good as gastric banding or full stomach-stapling surgery. Competing with drugs will be a harder challenge.

Gastric balloons available in Europe

Company	Device/drug	CE mark date	FDA approval date
Apollo Endosurgery	Orbera	1997 (as BioEnterics Intragastric Balloon)	August 2015
ReShape Medical	ReShape Duo	2007	July 2015
Obalon	Obalon Therapeutics	Prior to July 2012	-
Spatz FGIA	Spatz3	2012	-
Helioscopia	Heliosphere BAG	Prior to October 2014	-
Allurion Technologies	Elipse	December 2015	-

Sources: EvaluateMedTech, FDA, Bernstein

To contact the writer of this story email Elizabeth Cairns in London at elizabethc@epvantage.com or follow [@LizEPVantage](https://twitter.com/LizEPVantage) on Twitter