

## The balloon goes up for Apollo and Reshape



[Elizabeth Cairns](#)

An FDA warning letter spurred by the deaths of four obesity patients implanted with Apollo Endosurgery’s Orbera intragastric balloon and another of a patient given Reshape Medical’s similar device has knocked a quarter of the values off the former company. Though the FDA stated that it was unable to attribute the deaths to the balloons definitively this is likely to hit both companies’ top lines.

The third company to sell an intragastric balloon in the US might conceivably benefit. Obalon Therapeutics’ device is inflated with air rather than fluid, and as the only balloon to escape the FDA’s warning it could take share from Orbera, the current market leader.

[The FDA has identified](#) four deaths with Orbera and one with ReShape of which it could not identify the root cause; neither was it able to attribute the deaths definitively to the devices or the insertion procedures. It added that it had received two additional reports of deaths to which a definite cause could be attributed: one gastric perforation with Orbera and one oesophageal perforation with ReShape.

The FDA’s Maude adverse events database has no record of deaths associated with Obalon. The agency confines its warning to “liquid-filled” balloons; Orbera and ReShape are filled with saline, whereas Obalon is inflated with nitrogen-sulphur hexafluoride gas.

**Summary of deaths in patients with intragastric balloons**

Company	Device	Location	Date of death	Time between procedure and death
Apollo Endosurgery	Orbera	Brazil	January 29, 2016	<a href="#">10 days</a>
Apollo Endosurgery	Orbera	US	March 16, 2016	<a href="#">31 days</a>
Apollo Endosurgery	Orbera	Brazil	May 10, 2016	<a href="#">3 days*</a>
Apollo Endosurgery	Orbera	UK	Unknown (Nov 2016 or earlier)	<a href="#">3 days</a>
Apollo Endosurgery	Orbera	Mexico	April 11, 2017	<a href="#">3 days</a>
Reshape Medical	ReShape	Unknown	March 20, 2016	<a href="#">33 days**</a>
Reshape Medical	ReShape	Unknown	May 10, 2017	<a href="#">Unknown</a>

*Source: Apollo Endosurgery and FDA Maude database; \*death caused by gastric perforation; \*\*death caused by oesophageal perforation.*

Still, it cannot be said for certain whether the means of inflating the balloons is the cause of the patient deaths. The implantation procedures are also similar for Orbera and ReShape, but again Obalon differs: it is swallowed rather than being placed using an endoscope. It is important to note that the FDA has not ruled out the implantation procedure as a factor in the deaths.

### Reshaping the market?

As the only listed company, and the manufacturer of the market-leading balloon – more than 220,000 Orbera balloons have been distributed, according to Roth analysts – Apollo has the most to lose. Its share price dropped 26% in response to the news.

How much ground Obalon can seize from its competitors is not clear. A comparison of the results of the pivotal US trials of these devices appears to put Orbera way out in front, allowing a percentage weight loss around twice as great as those with ReShape and Obalon. This puts it on a par with many obesity drugs: Vivus's Qsymia showed a placebo-adjusted weight loss of around 8.5% in its pivotal trial.

<b>Gastric balloons in the US</b>			
<b>Company</b>	Reshape Medical	Apollo Endosurgery	Obalon Therapeutics
<b>Device</b>	ReShape	Orbera	Obalon
<b>US approval date</b>	July 28, 2015	August 5, 2015	September 8, 2016
<b>Fill method</b>	Saline	Saline	Nitrogen-sulphur hexafluoride gas
<b>Implantation method</b>	Endoscopy	Endoscopy	Swallowing
<b>Approval indication</b>	BMI 30-40 with comorbidities	BMI of 30-40	BMI of 30-40
<b>Pivotal trial name</b>	Reduce	IB-005	Smart
<b>Trial ID</b>	NCT01673698	NCT00730327	NCT02235870
<b>Placebo-adjusted total weight loss at 6mth (%)</b>	3.50	6.90	3.27

*Source: FDA approval labels.*

It is still a long way off the results seen with bariatric surgery, however. Gastric bypass typically permits patients to lose around 30% of their bodyweight. And surgery is reimbursed by Medicare and insurers in many cases, whereas gastric balloons are almost always paid for out of pocket in the US.

This means patients have a great deal of say in which device they use. News of patient deaths so soon after implantation could have a major effect on the sales of these products, whether a definite link emerges or not.

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