

## Obalon balloon for obesity



### TECHNOLOGY

The Obalon balloon is a gas filled gastric balloon that is intended to aid weight loss in people with a BMI of 27 or above by making the patient feel full faster. The Obalon balloon was developed by [Obalon Therapeutics](#), and is distributed in the UK by [Purple Surgical UK](#).



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The Obalon balloon is enclosed in a gelatine capsule the size of a large pill, which is attached to a micro-catheter. Under clinical supervision, the patient swallows the capsule and receives a x-ray to ensure the capsule has entered the stomach. Once in the stomach, the outer layer of the capsule dissolves releasing the Obalon balloon inside. The balloon is then inflated with nitrogen gas via the micro-catheter. Once the balloon is inflated, the micro-catheter is detached and removed via the mouth releasing the balloon to sit at the top of the stomach. The patient is able to return to normal activities immediately after placement.

Obalon balloons are licensed to be used for 12 weeks and the patient can have up to three balloons placed within the treatment period to facilitate greater weight loss. After 12 weeks, the balloon(s) is/are removed during an endoscopy procedure that takes about 15-30 minutes and may require sedation.

The Obalon balloon was CE marked in April 2012. It has been available for private and NHS clinical use in the UK since January 2014, subject to local funding arrangements.

### POTENTIAL FOR IMPACT

Obesity is associated with an increased risk of a number of chronic diseases including type 2 diabetes, heart disease, hypertension and stroke. Current NHS treatments for obesity include weight management programmes, pharmacological therapy and weight-loss surgery e.g. gastric banding and gastric bypass. In addition, intra-gastric balloons that are placed using an endoscope are available on the NHS for very obese (BMI  $\geq 40$ ) patients.

The company claim that a key innovative feature of the Obalon balloon is that it does not need to be placed using an endoscope. It also does not require sedation to place the

balloon, thus providing patients with a non-surgical alternative to current treatment options. In addition, only one endoscopy procedure is needed to remove the balloon(s) at the end of the 12 week treatment. Treatment using endoscopes is quicker and cheaper than bariatric surgery, and can be performed in an outpatient setting, thereby removing long recovery times and reducing hospital stays.

The company claim Obalon facilitates controlled weight loss with minimal impact on the patient's day to day life in a relatively short period of time by making the patient feel fuller faster and therefore consume fewer calories. However, the company highlight that the best results are obtained in combination with sensible diet, reduced calorie intake and exercise. As the treatment is only temporary and for a short period of time, once the balloons are removed there is the potential for patients to regain weight if they do not make long-term changes to their lifestyle. Treatment with Obalon balloons currently costs £2,995 for a two balloon treatment and £3,995 for a three balloon treatment.

### EVIDENCE

#### PUBLISHED PAPERS AND ABSTRACTS

Mion F, Ibrahim M, Marjoux S *et al.* Swallowable Obalon gastric balloons as an aid for weight loss: a pilot feasibility study. *Obesity Surgery* 2013;23(5):730-733.  
<http://www.ncbi.nlm.nih.gov/pubmed/?term=23512445>

Genco A. P.269 Novel, non-invasive, swallowable device for weight loss in overweight and light obese patients. Results of the European Obalon study group early experience. *Obesity Surgery* 2013;23:1183-1184.  
<http://link.springer.com/article/10.1007/s11695-013-0986-z>

Lagardere AO, Martinez A, So M *et al.* O-101 Weight loss and metabolic improvement using a swallowable, volume-titratable gastric balloon system. *Obesity Surgery* 2012;22:1170-1171.  
<http://link.springer.com/article/10.1007/s11695-012-0665-5>

Lagardere AO, Martinez A, So M *et al.* O-102 A less invasive gastric volume reduction with safe and effective titration. *Obesity Surgery* 2012;22:1171.  
<http://link.springer.com/article/10.1007/s11695-012-0665-5>

#### COMPLETE UNPUBLISHED STUDIES

European study to evaluate preliminary safety and efficacy of multiple Obalon gastric balloons for 12 weeks as an aid for weight loss.  
<http://www.clinicaltrials.gov/ct2/show/NCT01718886> Accessed 15 July 2014.

Pilot study to evaluate a novel gastric space occupying device.  
<http://www.clinicaltrials.gov/ct2/show/NCT01444274> Accessed 15 July 2014.

Study to evaluate novel gastric space occupying device.  
<http://www.clinicaltrials.gov/ct2/show/NCT01288456> Accessed 15 July 2014.

### ONGOING STUDIES

WHO International Clinical Trials Registry. A non-invasive swallowable device for weight loss and obesity-related comorbidities.

<http://apps.who.int/trialsearch/Trial.aspx?TrialID=ISRCTN53040076> Accessed 15 July 2014.

ClinicalTrials.gov. Obalon in children with severe obesity.

<http://clinicaltrials.gov/show/NCT02137330> Accessed 15 July 2014.

### COMPANY INFORMATION

The company have been in discussions with bariatric consultants in the UK, who may be interested in adopting Obalon as a treatment bridge for patients that are required to lose weight to either achieve a better surgical outcome for a different condition, or to reduce the chance of complications due to excess weight that could be experienced under general anaesthetic for any form of surgery.

### INFORMATION FROM

This Alert is based on information from the company and a time-limited internet search.