



When diets
alone fail...



At last...

...a helping hand for the thousands of overweight patients who require more than just drug therapy or dietary advice alone.

Orbera™
intra-gastric balloon



The ORBERA[®] intragastric balloon*

A tried and tested,
non-pharmaceutical treatment for the
overweight patient who may refuse or not qualify
for surgical intervention

The ORBERA System is a soft, silicone intragastric balloon, designed to induce weight loss by partially filling the stomach to help overweight** patients achieve a feeling of satiety.

Feeling fuller, more quickly after small meals may help make it easier for these patients to change their dietary habits and ready to adopt a new, healthier lifestyle during the six months the balloon is in place.



*Previously known as the BIB[™] Intragastric balloon

** Patients with a BMI of ≥ 27 kg/m²

Each physician and patient should evaluate the risks associated with endoscopy and intragastric balloons and the possible benefits of a temporary treatment for weight loss prior to use of the ORBERA System.

Please refer to the full DFU for further information regarding the risks and benefits. A copy will be provided on request from APOLLO or your sales representative.

A realistic approach to weight loss

- ☾ Diets alone rarely succeed in changing long-established eating habits
- ☾ The ORBERA System gives patients a chance to lose weight and develop a more healthy lifestyle*
- ☾ Suitable for overweight or moderately obese patients with a BMI of 27 or more who have failed to achieve and maintain weight loss with a supervised weight control programme alone

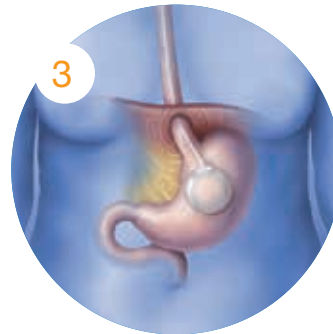
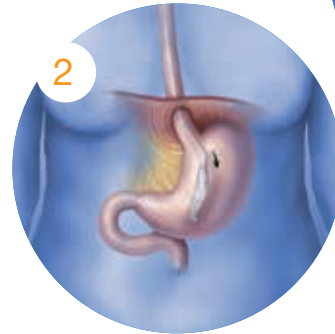




- Smooth, silicone elastomer balloon
- Endoscopically placed in the stomach and inflated with saline
- Soft, flexible catheter assembly with silicone sheath, filling connector and guide wire for easy insertion
- Endoscopically deflated and removed with specially designed tools
- Maximum placement period of up to 6 months

For inner confidence






Straightforward, non-surgical procedure



The 'ideal' intragastric balloon

In 1987 a group of leading experts from around the globe met to examine all aspects of patient treatment with the intragastric balloon.

These 75 experts agreed the following characteristics of an ideal intragastric balloon, commonly known as the 'Tarpon Springs Criteria'¹

Expert recommendations ¹ Gastric balloons should:	The ORBERA System - Designed specifically to meet these criteria
Be effective at promoting weight loss	Yes 
Be capable of adjustment to various sizes	Variable fill volume from 400-700cc to suit a wide range of patients 
Be filled with liquid	Saline filled to induce the appropriate feeling of satiety for each patient 
Contain a radiopaque marker that allows proper follow-up of the device if it deflates	A radiopaque valve allows location under X-ray 
Be constructed of durable materials that do not leak, with smooth surface and low potential for causing ulcers and obstructions	Round, smooth, high quality silicone shell with proven durability and minimal irritation to the stomach wall for increased acceptability* 

Design
reliability
you can trust

¹Recommended in combination with use of Proton Pump Inhibitor (PPI) treatment

85% of patients succeeded in losing over 20% of their excess weight²

In a 6 month, prospective, multicentre, non-controlled study, 323 patients showed highly significant ($p < 0.001$) reductions in the following outcomes compared to baseline:

- Mean weight loss:
-15.2kg (± 10.5 kg)
- Percentage Excess Weight Loss (EWL):
48.3% (± 28.1 %)
- Mean reduction in Body Mass Index (BMI):
-5.3 kg/m² (± 3.4 kg/m²)

Similar results were found in a large European retrospective study involving 2,515 obese patients³

Results 6 months after the ORBERA balloon placement:

- Percentage EWL:
33.9%
- Mean reduction in BMI:
-4.9kg/m²

Orbera™
intra-gastric balloon

Clinical success backed by weight of evidence

85%
Successful weight loss*

*Success was defined as $>20\%$ excess weight loss (EWL)

The ORBERA System delivers significantly superior weight loss compared to diet alone⁴

A retrospective study compared the outcomes of the ORBERA System placement with diet regimen alone in 130 overweight patients with similar BMIs at baseline over an 18-month period.

Weight loss comparison at 6 and 24 month follow-up ⁴				
Results	6 months		24 months	
	*The ORBERA System	Diet	**The ORBERA System	Diet
Weight loss (kg)	16.7 (±4.7)	6.6 (±2.6)	11.2 (±4.9)	1.5 (±2.9)
BMI reduction	6.1 (±4.3)	2.5 (±2.1)	3.9 (±3.1)	0.7 (±0.8)
%EWL	33.9 (±18.1)	24.3 (±17.0)	21.3 (±19.7)	2.9 (±3.1)

* At time of removal

**18 months post-removal

- Significantly better weight loss results were observed in patients treated by the ORBERA balloon compared with the diet-treated controls at removal ($p < 0.01$) and at 18 months post-removal ($p < 0.001$)
- Furthermore, the dropout rate was significantly lower in patients treated with the ORBERA System (1% vs 18% diet-treated patients, $p < 0.001$)

This study also indicated that the influence of the ORBERA System treatment on patients' behaviour is at least partially maintained after removal of device.

Most patients adjust to the ORBERA System within a few days

- Across the treatment period, the ORBERA balloon was generally well tolerated. Common adverse effects include nausea, vomiting and belching within the first 3-5 days after placement, the intensity of which can vary from patient to patient, usually disappearing within a few days²
- Clinicians report that patients come to regard the ORBERA balloon in a very positive manner once transient side effects have subsided, judging it “good”, “very good” or “excellent”²

Well tolerated for the majority of patients



Minor complications may include:

Reflux oesophagitis (controllable with PPI therapy) and transient symptomatic gastric stasis

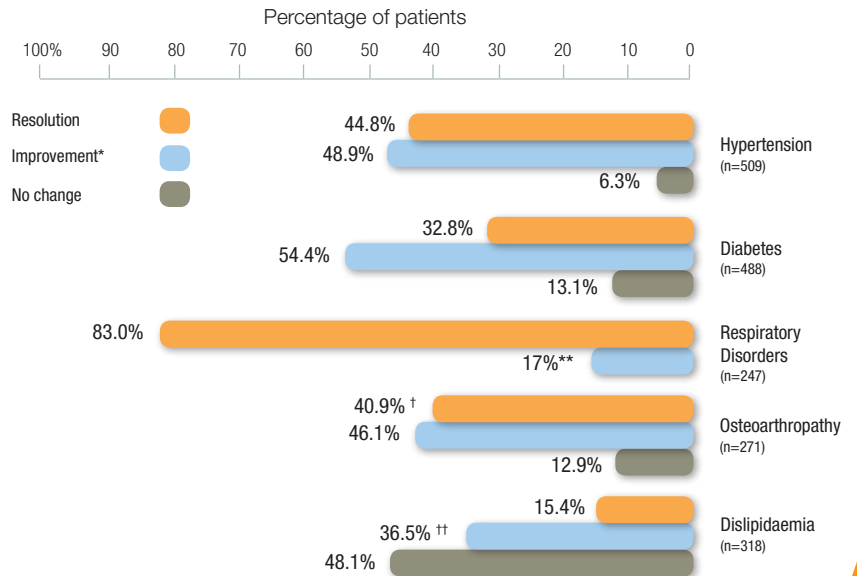
Contraindications include:

Patients who have had previous gastrointestinal surgery, psychiatric disorders, non-cooperative patients, alcoholics and drug addicts. Pathology that includes large hiatus hernia, inflammatory disease of the gastrointestinal tract including oesophagitis and gastric ulceration.

Please refer to the full DFU for further information.

A large European study also demonstrated a significant influence on baseline co-morbidities³

Change in co-morbidities at time of the ORBERA balloon removal (6 months in 1,394 patients)



* Lower drug dosage or shift to other therapy

** Sleep apnoea disappeared, but patients remained tachypneic after physical activity

† Patients without radiological evidence of arthritic modification

†† Improvement prevalently linked to normalisation of tryglicerides (cholesterolaemia less influenced)



89%
co-morbidities
resolved/improved³

Additional **advantages** of the ORBERA System

Pre-surgical weight loss

The greater incidence of obesity is becoming a daily challenge in surgical practice. Morbidly obese patients are at increased risk of post-operative complications.⁵

“*[The ORBERA System] has played an essential role in the preoperative treatment of morbidly obese patients who are scheduled to undergo bariatric or other elective surgery by minimizing morbidity and mortality risks⁴*”



Better short-term weight loss option than Laparoscopic Sleeve Gastrectomy (LSG)⁶

In a study that compared the efficacy of LSG (n=40) with the ORBERA System intragastric balloon (n=80), it was found that both procedures offered

☾ Comparable weight loss at 6-month follow-up

☾ Comparable reductions in co-morbidities at 6-month follow-up

however,

☾ LSG is irreversible and carries all related risks of anaesthesia, laparoscopic surgery and digestive anastomosis

☾ The ORBERA System presents a very low rate of minor complications and is fully reversible

“*For all these reasons, at this time, we consider [The ORBERA System] a better option than LSG as a first-step procedure in the short term (12 months)⁶*”

The ORBERA System - Extra help to fulfill their hopes

- ☾ Patients achieve greater weight loss with the ORBERA System than with diet alone ^{4,5}
- ☾ Large-scale studies support excess weight loss between 34 and 48% ^{2,3}
- ☾ Simple endoscopic placement and removal
- ☾ Established safety profile³ with over 10 years proven experience
- ☾ Shown to reduce co-morbidities
- ☾ Proven role in reducing the risks of elective surgery



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Caution: This device is restricted to sale by or on the order of a physician. The ORBERA System intragastric balloon contains no latex or natural rubber materials.™ mark owned by Apollo Endosurgery, Inc. © 2015 Apollo Endosurgery, Inc. Austin, TX. All rights reserved.

References:

1. Schapiro M *et al.* Obesity and the gastric balloon: a comprehensive workshop. *Gastrointestinal Endoscopy* 1987; **33**(4): 323-327.
2. Sallet JA, Marchesini JB, Paiva OS *et al.* Brazilian Multicentre Study of the Intragastric Balloon. *Obesity Surgery* 2004; **14**:991-998.
3. Genco A, Bruni T, Doldi SB *et al.* BioEnterics Intragastric Balloon: The Italian Experience with 2,515 Patients. *Obesity Surgery* 2005; **15**:1161-1164.
4. Genco A, Balducci S, Bacci V *et al.* Intragastric Balloon or Diet Alone? A Retrospective Evaluation. *Obes Surg* 2007; (DOI 10.1007/s11695-007-9383-9).
5. De Waele B, Reynaert H, Urbain D *et al.* Intragastric Balloons for Preoperative Weight Reduction. *Obesity Surgery* 2000; **10**:58-60.
6. Genco A, Cipriano M, Materia A *et al.* Laparoscopic sleeve gastrectomy versus intragastric balloon: a case-control study. *Surg Endosc* 2008; (DOI 10.1007/s00464-008-0285-2).