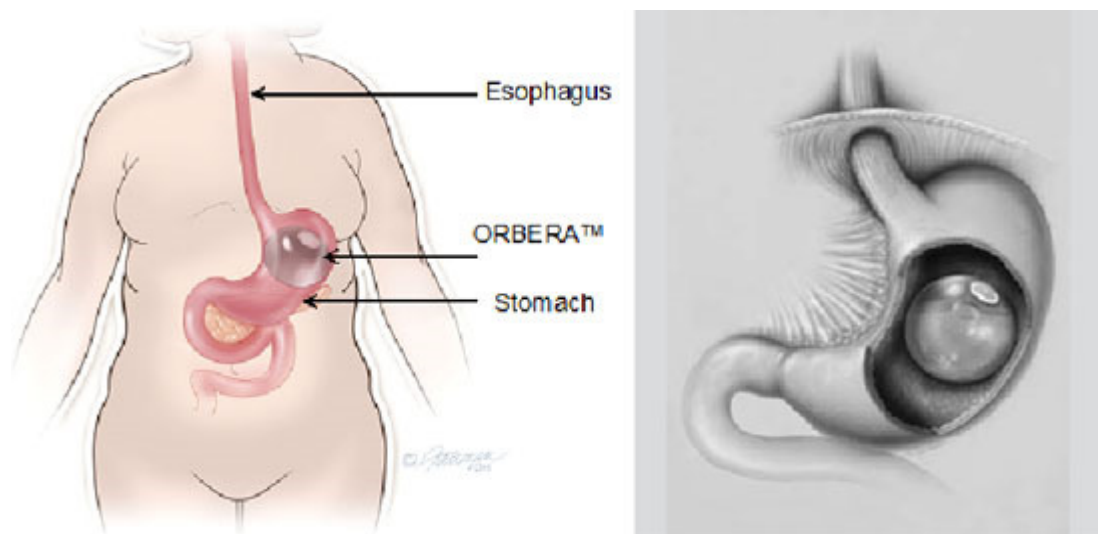


ORBERA™ INTRAGASTRIC BALLOON SYSTEM

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What is it?

The ORBERA™ Gastric Balloon is a reversible, incision free, twenty minute weight loss procedure. The concept is simple as a deflated silicone gastric balloon is placed into the stomach through the mouth, using a minimally invasive endoscopic procedure, while the patient is under mild sedation. Once in place, the balloon is filled with salt water (saline) so that it expands into a spherical shape. The balloon can be filled with different amounts of saline (from 400 to 700 cc) to best match the patient's body structure. The balloon can be left in the stomach for up to six months.

How does the intragatric ballon work?

Once in place, the intragastric balloon is filled with saline to partially fill the stomach, helping a patient to feel less hungry, so that they may consume smaller portions of food and experience similar satisfaction to what they would have previously experienced after consuming a larger meal. It also causes the food to stay in the stomach longer so you feel full for a longer period of time. Most weight is lost in the first three months, but because the intragastric balloon stays in for six months, a patient will learn the right amount of food to eat to maintain new weight long-term.

When is it used?

The device is used in obese adult patients who have a Body Mass Index (BMI) of 30-40 kg/m² who have been unable to lose weight through diet and exercise. It is also used for people who are not suitable for other forms of weight loss surgery, or who do not accept the risks involved with weight loss surgery.

The intragastric balloon may also be used to assist in reducing weight prior to surgery, therefore reducing the risks associated with surgical procedures on overweight patients.

When should it not be used?

The device should not be used in patients who:

- have a BMI of less than 27
- already have an intragastric balloon
- have had prior gastrointestinal or bariatric surgery
- have any inflammatory disease of the gastrointestinal tract
- have potential upper gastrointestinal bleeding conditions
- have a large hiatal hernia
- have a structural abnormality in the esophagus or pharynx
- have serious esophageal motility disorders
- have a gastric mass
- have a severe clotting or bleeding disorder (coagulopathy)
- have liver failure (hepatic insufficiency) or cirrhosis
- are known to have or suspected to have an allergic reaction to materials contained in the ORBERA™ system
- have any other medical condition which would not permit elective endoscopy
- have a serious prior or present psychiatric illness
- have alcoholism or drug addiction
- who are unable or unwilling to take prescribed proton pump inhibitor medication for the duration of the device implant
- are unable or unwilling to participate in a medically supervised diet and behavior modification program with routine medical follow-up
- are receiving aspirin, anti-inflammatory agents, blood thinners (anticoagulants) or other gastric irritants
- are pregnant or breast-feeding

What will it accomplish?

During a clinical study, the group of people who used the ORBERA Intra gastric Balloon lost more weight than those who did not. The study included a total of 255 patients who were followed for one-year. During that period, 125 patients received the device and had it in place for six months. After the device was removed, they were followed for an additional six months, 130 patients participated in a 12-month behavior modification program and did not receive the device.

Patients with ORBERA lost an average of 21.8 pounds (10.2% of their body weight) after the device had been in place for six months. Three months after the device was removed (9 months after device placement), patients who received the device maintained an average of 19.4 pounds weight loss. The 130 patients who participated in the behavior modification program but did not receive the device lost an average of 7.0 pounds (3.3% of their body weight).

What is the ORBERA® journey?

Placement

The intragastric balloon is introduced into the stomach through the mouth by a gastroscopy procedure. This does not require any surgery. It performed under sedation or general anesthesia. The physician inserts an endoscopic camera (gastroscope) into the stomach, if no abnormalities are observed, the doctor proceeds with placement of the balloon through the mouth and down the oesophagus into the stomach. Once inside the stomach, the intragastric balloon is filled with approximately 400-700 ml of the saline solution or air and then remove the catheter. The balloon has a self-sealing valve, it floats freely inside the stomach. When full, the gastric balloon is too large to pass into the bowel.

A qualified specialist gastroenterologist performs this procedure in conjunction with an anaesthetist and trained nursing staff.

Placement of the intragastric balloon takes approximately 20 to 30 minutes, after which patients are monitored by specialist nursing staff in the recovery room. As this is a 'day-only' procedure, patients are generally escorted home within two hours after intragastric balloon insertion.

Recovery time varies from patient to patient; patients usually return to work in around three to five days after the procedure. A course of oral medication to reduce stomach acid may reduce the possibility of stomach irritation and damage to the intragastric balloon.

Recovery a liquid diet only

In the first few days following the procedure, patient may feel uncomfortable as the stomach gets used to the presence of the intragastric balloon.

Predictable side effects most patients experience include nausea, vomiting and gastric discomfort over the first week. These symptoms can be managed by the medications provided by the doctor. These conditions are normal and should be expected. It is critical that the patient should drinks plenty of water during the first few days and avoid eating any solid foods.

Liquid diet for the first three days, which might include:

- Juices
- Milk
- Thin soups or broths
- Gelatins.

The following foods will need to be avoided:

- Coffee
- Fizzy drinks
- Fatty foods
- Chocolate
- Ice cream.

Moving into solid food

After a few days on a liquid diet, patient be ready to begin the transition to solid foods. Start with semi-solids and gradually move to fully solid foods.

Exercise guidelines

Patients can start exercising under the advice from their doctor and support team, as soon as they feel well enough. This is usually about two weeks after their procedure. An exercise program should have been agreed on before the placement was carried out, ideally with ongoing motivation from an exercise therapist.

Important things to remember for exercising:

- Don't engage in any physical activity for the first 24-48 hours
- Drink cold liquids in small amounts, beginning with a teaspoon, and slowly increase the amount of the liquid.
- If liquid is taken in large amounts there is a higher risk of nausea and vomiting

What happens if the intragastric balloon deflates spontaneously?

This is a very rare event but if the intragastric balloon should spontaneously deflate, there may be no longer a feeling of satiety and the physical sensation of the balloon will disappear. If suspect this case, notify the clinic as soon as possible. A simple abdominal x-ray can determine whether either has occurred. The deflated intragastric balloon should be removed with a gastroscopic procedure similar to how the balloon was inserted.

The doctor will place a coloured dye inside the intragastric balloon called Methylene Blue. This will help to clearly identify early deflation or leakage as it will change the colour of urine to green. The intragastric balloon is small enough that it may pass through the intestines and leave the body naturally but there have been some cases in which it has had to be removed from the bowel surgically.

Removal of the orbera intragastric balloon

The intragastric balloon is removed in the same way it was placed in the stomach, via the oesophagus and mouth. Using an endoscopic camera, the doctor introduces a catheter through the mouth and into the stomach. The intragastric balloon is then punctured and deflated. Once the intragastric balloon is deflated it can be grasped and removed. This is no different to a simple gastroscopy or upper endoscopy procedure.

Preparation for removal of the ORBERA® intragastric balloon with:

- No solid food 24 hours prior to the procedure
- No liquids 12 hours prior to the procedure

Life after Gastric Balloon

The stomach will return to normal after the gastric balloon is removed. Advocates believe that it can still result in lasting and ongoing weight loss after removal because it helps exact behavioral changes; their theory holds that people get used to eating smaller portions of food and are therefore more inclined to continue to eat in this manner long after the balloon is removed.

References

1. <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm457416.htm>
2. <http://www.orbera.com>.
3. <http://orberaweightlossballoon.com>.
4. <http://bariatric.stopobesityforlife.com/obesity-surgery/correcting-obesity/procedures/reshape-orbera-gastric-balloon>.
5. <http://www.yourbariatricsurgeryguide.com/gastric-balloon>.