



A Treatment Guide

A new **beginning**
needs a new approach



Are diets or slimming pills not working for you?

If you are one of the thousands of people who have tried dieting the 'traditional' way without success, then you may need help of a different kind.

It's a fact that diets alone rarely change long-term eating habits. Many people find themselves in a cycle of losing and gaining weight, as they switch from one failed diet to another – the so-called 'yo-yo' effect. Others may resort to slimming drugs or diet suppressants, but even then unpleasant side effects can make it difficult to stay the course.

There is another option for people who want to lose weight but don't want or qualify for more drastic measures like surgery.

Before deciding which procedure may be right for you, it's important to discuss available options with your physician.

Welcome to the
ORBERA® System

The ORBERA System is a tool that is designed to give you the extra help you need to adjust to a healthier lifestyle.

The ORBERA System is a soft, saline filled silicone balloon that is placed in the stomach for up to six months. The balloon is designed to partially fill your stomach, giving you a feeling of fullness. In medical terms this is called 'satiety'. It will not only make you feel less hungry, but feel fuller more quickly after small meals.

And because you will feel more satiated, you should find it easier to make the changes to your diet and lifestyle that will help you keep the weight off once the balloon is removed.

The ORBERA System does not involve surgery nor does it require long-term drug therapy. It is placed and removed during a 20-30 minute 'endoscopic' procedure, during which you will be mildly sedated.

Once the balloon is in place, your clinic should be able to provide you with dietary advice and support to help you make the changes to your diet and lifestyle that are necessary to help you achieve your weight loss goals.

Interested in finding out more? *Then, please read on.*



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.

What should my **ideal** weight be?

Usually, people instinctively know when they have reached their 'ideal' weight.

This is the weight at which people generally feel good about themselves, feel healthy and energetic, feel they can wear what's 'in-fashion' without feeling too self-conscious in public.

The most common measurement used for indicating whether a person is overweight is **Body Mass Index** (BMI).

You can work out your own BMI by using the following calculation:

$$\text{kg/m}^2 = \text{BMI}$$

Your weight in kilograms divided by the square of your height in metres

BMI CLASSIFICATION	
18-24.9	Normal
25-29.9	Overweight
30-34.9	Obese
35-39.9	Severely Obese
40 or above	Morbidly Obese



So is the ORBERA System **right** for me?

If you have a BMI of 27* or more, the ORBERA System could be the ideal solution for you.



In addition, there are certain medical reasons for which you may not be eligible for treatment with the ORBERA System. These may include:

- Previous history of upper gastro-intestinal surgery, obstruction, adhesive peritonitis or large hiatus hernia
- Severe renal, hepatic or pulmonary disease diagnosis
- Chronic, long-term steroid treatment
- Unwillingness to adopt the dietary habits critical to the success of the therapy
- Drug or alcohol addiction in the last 12 months
- Pregnancy or breast feeding

***The ORBERA System is not licensed for use in patients with a BMI lower than 27.**

This information is only a guide. Your doctor will be able to give you a much more accurate health assessment based on your BMI and other relevant factors and will ultimately determine whether you are suitable for treatment.

As with all medical procedures, there are potential risks of unforeseen, unknown or adverse reactions to medications and the procedure itself. Please discuss your questions and expectations about the ORBERA System with your doctor in order to properly evaluate the benefits versus the possible risks.

About the **procedure**

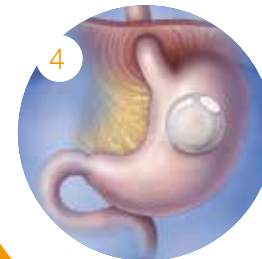
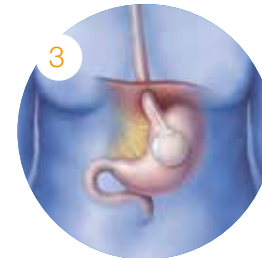
You'll be lightly sedated whilst your clinician uses an endoscope to pass a deflated gastric balloon into your stomach. Once in place, it's injected with saline (salty water) via a small tube. The balloon valve seals when the tube is withdrawn.

The whole process normally takes around 20-30 minutes.

You'll rest in the clinic for 1-2 hours for observation before being discharged. You can then be taken home.

For the first few days, as your stomach adjusts to the balloon, you'll almost certainly feel uncomfortable. You may well experience nausea, bloating, diarrhoea and cramping. These side-effects are temporary and normal. If necessary, your clinician can prescribe suitable medication to manage them.

Having the balloon removed is very simple. Whilst mildly sedated, an endoscope is used to deflate it before it's withdrawn. You'll be home within two or three hours. Most people need little or no time off work.



How much **weight** can I expect to lose?

Patients treated with the ORBERA balloon can expect to have significant weight loss during the six months the balloon is in place.

The following weight loss results were achieved in published clinical studies using the ORBERA balloon.

The amount of weight you lose and how long you maintain that weight loss will depend on how well you adopt long-term lifestyle changes related to eating and exercise. Your clinic should provide dietary and lifestyle advice to help you make the changes needed.



Brazilian Study, 2004

323 patients;
average weight loss
after 6 months:

15kg¹

Large European Study, 2005

2,515 patients;
average weight loss
after 6 months:

20kg²

The ORBERA System is a tool to help you take control of your weight and give you the kick-start to a healthier lifestyle. Studies show that patients who have undergone The ORBERA System procedure are more likely to maintain their weight loss over a longer period of time than compared to diets alone.⁹

Getting prepared

If you're suitable for the ORBERA System and you want to proceed, your clinician will arrange a consultation before the procedure. You'll be given specific dietary instructions to follow, including instructions if you take prescription medication. You can also discuss the procedures first hand.

For a basic overview, here's some general guidance.



Pre-procedure

Don't eat food or drink any liquids for **12 hours** before the procedure. If you do, your clinician may not be able to proceed with your appointment

Since you'll be on a liquid diet for three days after the procedure, you'll be told to have certain food and drinks available at home. These may include:

- ☉ Juices
- ☉ Thin soups
- ☉ Milk
- ☉ Jellies



There are a few other things you need to plan for in advance:

- ☉ When you have your procedure, you'll also need to be accompanied to and from the clinic. You'll also need someone to stay with you for the first 24 hours.
- ☉ If you look after small children, arrange for childcare for at least 3 days.
- ☉ If you're staying in a hotel, please check in before your procedure and advise the clinic of your room number. We recommend that you have everything you need ready in the room before you are discharged from the clinic. Someone should stay with you for the first 24 hours.

On the **day**

First of all, try to relax and be positive!
This is the day that your life can start to change.

- Remember not to have any food or drink for at least 12 hours before.
- Wear comfortable clothing and shoes.
- You'll be given a prescription for any medicines to be used after the procedure.
- Once the procedure is over you will remain in the clinic for observation until your doctor discharges you.
- Your doctor will let you know if you need someone to take you home or to travel with you on public transport after your procedure.

Once you're back home.

At this point you have taken the first important step in a journey that can change your life. The kick-start has begun and today is the start of a process that will help you retrain your appetite and achieve your weight loss goals. You will have a tough few days ahead as you adjust to the balloon, but just remind yourself of the reasons you chose to do this and of the new you that is waiting at the end of this road.



First steps:

- Ensure you follow the advice provided by your clinician.
- Drink cold liquids in small amounts, beginning with a teaspoon, and slowly increase the amount of the liquid as you are able. If you drink large amounts there's a higher risk of nausea and vomiting.
- Rest. Don't do any physical activity for the first 24 hours.

The first few days:
adjusting to the ORBERA System

Week 1: Full Fluid Diet

The first few days will be uncomfortable as the stomach gets used to the presence of the balloon. You may experience further nausea, vomiting, bloating, diarrhoea and cramping until your body adjusts. These conditions are normal and should be expected. Your physician will provide strict instructions for your hydration regimen during this period. In the days that follow it is critical that you drink plenty of water and avoid eating any solid foods.



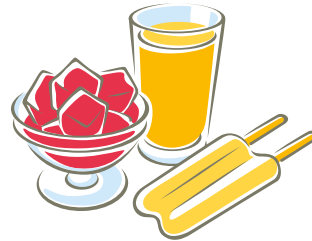
Remember:

- Drink slowly, taking small sips
- Wait between the sips for a minute or two
- Don't drink more than 100 ml at once
 - Wait for at least 10 minutes between drinks
- Your total fluid intake should be **more than** 2.0 litres (8 cups) per day



Fluids to include:

- ☾ Low-calorie, low-acid fruit juices, such as apple juice
- ☾ Weak tea or coffee, preferably decaffeinated
- ☾ Clear broth or soup
- ☾ Low-calorie gelatins (e.g. fruit jelly)
- ☾ Low-fat yoghurt drinks
- ☾ Skimmed milk



You may want a 1-week supply of a meal replacement shake to help you meet your calorie and protein needs for the day (ask your clinician for more information)

Week 2:

Pureed, soft and solid foods

Your stomach is starting to adapt to the gastric balloon. So this is a time when it's important to 'listen' to your body.

The transition from PURÉE to SOLID foods should take approximately one week, but only progress when you can tolerate next stage foods comfortably.

Always try to eat slowly, chewing food very well.

Purée foods (for up to 3 days)

Once you're tolerating fluids well, you can start introducing purée foods into your meals. In many cases you'll be able to use the same foods the rest of your family is eating by puréeing them in a blender or food processor.

Also, by this stage you should be incorporating protein into every meal. Don't worry if you aren't able to eat all that much, and remember to stop eating if you feel discomfort or pressure.



Remember:

Don't forget to drink plenty of fluids all the time your balloon is in place.

Soft foods (for up to 4 days)

This stage prepares you to finally return to solid foods. Again remember to eat slowly and chew your food very well. Choose foods that are low in fat, calories and carbohydrates.

As you are learning to listen to your body during this transition, pay attention if you develop feelings of fullness, pressure or discomfort. These are signs that you should slow down or stop eating entirely in order to avoid vomiting.

Examples of suitable soft foods:

-  Bananas or other soft fruit
-  Porridge/oatmeal
-  Egg
-  Yoghurt
-  Cottage cheese
-  Canned tuna





Remember:

Use the **20/20** rule when eating. Food should be chewed at least **20** times and a meal should take **20** minutes or more to consume.



Solid foods

By now you're reaching the end of your dietary transition. You'll have resumed your normal activities and have begun retraining your appetite for a maintained and healthy weight loss. Here are some tips as you return to eating solids:

-  1 Introduce solid foods one at a time.
-  2 Try cooked foods first before hard/raw foods.
-  3 Limit or try to avoid bread, pasta, rice and other starches. These foods may stick to the balloon, causing bad breath.
-  4 Drink plenty of water and avoid eating and drinking at the same time; drink at least one glass ½ hour before each meal and two glasses ½ hour afterward to 'rinse' the balloon.

To succeed with your managed weight loss, it's vitally important that you follow the nutritional plan and lifestyle changes your clinician explained at the outset.

Whilst your ORBERA balloon is implanted, also be careful to note and report any unusual changes in the way you feel. If you feel nauseous for a longer period of time than the initial few days, let your clinician know immediately.



Healthy living starts here

The next 6 months

After the first two weeks, your body will have adjusted to the ORBERA balloon and you should be following a regular nutrition plan.

Your success will now depend on how committed you are to adopting the principles of good health into your daily life. You may receive instructions from your clinician on your nutrition regimen with calorie restrictions. You may also have further appointments scheduled with a nutrition expert to monitor your progress. If so, do make sure you attend every appointment.

Remember, the ORBERA balloon is only a 'training tool', like stabilisers on a bicycle. The ORBERA System gives you a window of opportunity to adapt to the lifestyle changes you must make in order to maintain your ideal body weight.

The following guidelines will help you be more successful.



A matter of balance

Eating a balanced diet is essential. It simply means including a variety of foods from all four food groups -vegetables and fruit, grain products, milk and alternatives, and meat and alternatives.



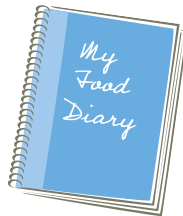
Read nutritional labels

Nutritional Information labelling is mandatory on all pre-packaged food to help you, as a consumer, make informed decisions. It's important that you note not only the calorie count, but also the portion size being used on the label.



Keep a food diary

It's extremely useful to keep a food diary. Besides providing a useful record, it keeps you aware of the choices you make during the day. In this way, you can see each week when you're doing well – and when you need to make more effort to achieve your goals.



Exercise matters

To lose the weight you want and keep it off, your body needs to become more active. It's the only way you'll burn the daily calories you consume, and potentially burn off some existing fat too. Don't panic: this doesn't mean running a daily marathon!

Even seemingly small changes – like taking the stairs instead of the lift – over time make a massive difference to your metabolic health and the daily calories your body burns.

Other basic tips to adopting a healthier lifestyle:

- Select low-fat and low-calorie alternatives
- Limit your fat, sugar, alcohol and salt.
- Increase your daily fibre intake
- Drink plenty of fluids, especially water





Moving on → having the ORBERA balloon removed

At six months (or perhaps even earlier), the ORBERA balloon will be removed. It's a 20-30 minute procedure, very similar to the one you experienced for placement.

During the removal procedure, you'll be sedated. Using an endoscope and small tube, your clinician will remove the saline fluid from the balloon before retrieving the deflated balloon from your stomach.

Following removal of the ORBERA balloon, very few people experience any side effects, but your doctor will keep you in the clinic for a couple of hours following removal so that any sedative effects have a chance to wear off, and he/she can check that you are fit to go home.

Important reminders

- ☾ No solid food 24 hours prior to the procedure
- ☾ No liquids 12 hours prior to the procedure
- ☾ Due to the effects of sedation, you may need to arrange for someone to drive you back home

Taking control - life after the ORBERA balloon

You have made a bold decision to take control of your weight, you took the first and most difficult steps to finding the new you.

Whilst in place, the ORBERA balloon has given you the extra support you need to achieve your weight loss goals and to ultimately look and feel better about yourself. Now, it's up to you to build on and sustain the changes you have made to the way you live.

Eat to live. Don't live to eat.

Remember that this is **NOT** a diet – it's a **lifestyle change**. Sustained success means staying committed to healthy eating, taking smaller portion sizes and pursuing an active lifestyle.

Recognise, too, that everybody has bad days. Just remember to do better tomorrow.

If you do overindulge, try not to panic. The most important thing is to understand why the lapse happened, and recognise the cause. Were you under pressure? Was it the social environment? Are you worried or depressed? If necessary, talk your feelings through with friends or family members. If you're concerned your healthy eating habits are deteriorating dramatically, consult your GP or a nutritional professional for advice.



Keep on **track**

Your clinic may provide dietary and lifestyle advice to help you maintain your good habits. Be sure to follow the advice as closely as you can. Here are a few final tips to help you on your way.

Avoid comfort eating

When things go wrong, it's often tempting to turn to food for comfort. **Don't.** Recognise the urge and resist it by doing something else that will make you feel better. If you must eat, eat sensibly. You'll be amazed at how much fresh vegetable and fruits can rejuvenate you and your spirit. Invest in a juicer and you also can quickly create delicious, hunger-satisfying nutrition-packed drinks.

Watch portion sizes

Healthy portion sizes keep the weight off. Stay conscious of your portion sizes especially when others are serving food to you. If you find yourself with a serving that's too large, eat what you would normally then stop. Don't feel compelled to try and clear your plate. Simply eating from a smaller plate can really help you manage how much you consume.

Stay busy and active

Taking regular exercise means you'll stay feeling good - both physically and mentally. Staying active not only burns calories and helps improve your cardiovascular health; it also shapes how you look. It's no coincidence that the compliments really will just keep coming - the more effort you make the longer you'll persevere.

Water is your friend

Keep track of how much water you drink. You should still be drinking at least 8 glasses a day. Drinking water keeps you feeling full, and stops you from overindulging when it's time to eat.

Good luck!

Now that you have reached your goal you can begin to enjoy life to the full. You have successfully made significant changes to your diet and to your lifestyle – it's something you can continue to build on, now and in the future.

After all, the ORBERA System was just the kick-start – the real hard work was down to you!



INDICATIONS FOR USE

The ORBERA System is indicated for temporary use in weight-loss therapy for overweight patients with a Body Mass Index (BMI) 27kg/m^2 or greater.

The ORBERA System is to be used in conjunction with a long-term supervised diet and behaviour modification program designed to increase the possibility of long-term weight loss maintenance.

The maximum placement period for the ORBERA System is 6 months, and it must be removed at that time or earlier.

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.

Physicians have reported the concurrent use of medications which reduce acid formation or reduce acidity. Silicone elastomer is degraded by acid. Moderating the pH in the stomach should prolong the integrity of the ORBERA System.

The materials used to fabricate this device have been tested according to ISO 10993, the International Standard for biological evaluation of medical devices.

References:

1. Sallet JA, Marchesini JB, Paiva OS *et al*. Brazilian Multicentre Study of the Intragastric Balloon. *Obesity Surgery* 2004; 14:991-998.
2. Genco A, Bruni T, Doldi SB *et al*. BioEnterics Intragastric Balloon: The Italian Experience with 2,515 Patients. *Obesity Surgery* 2005; 15:1161-1164.
3. 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).

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Caution: This device is restricted to sale by or on the order of a physician.

The ORBERA intragastric balloon contains no latex or natural rubber materials.
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