

endura  
Weight Loss Solutions



# TEMPORARY HELP TO JUMPSTART YOUR WEIGHT LOSS

**Orbera365™**  
Intragastric Balloon System



**PROVEN WEIGHT  
LOSS RESULTS<sup>2,3</sup>**

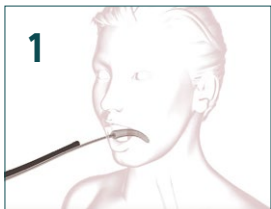


**12 MONTHS  
OF SUPPORT**

Orbera365™ is one of the procedures that is part of Endura Weight Loss Solutions from Boston Scientific.

# HOW ORBERA365™ WORKS

## THE MINIMALLY INVASIVE SOLUTION



1  
Deflated ORBERA365™ balloon is inserted through your mouth and into your stomach.



2  
A 50cc syringe is then used to fill the balloon with a sterile saline solution to the size of a grapefruit.



3  
The balloon takes up enough space in your stomach to support you in discovering portion sizes that work best for your body.

## UP TO 12 MONTHS LATER



4  
The balloon is removed up to 12 months later with a minimally invasive procedure.

# ORBERA365™ HELPS YOU ADJUST TO SMALLER PORTION SIZES AND DEVELOP EATING PATTERNS THAT MAKE YOU FEEL YOUR BEST



**12**  
months

## 12 MONTH PLACEMENT & ONGOING SUPPORT

Learn how to change your lifestyle and maintain the progress and positive habits you've built with the care and support of a team of experts over a period of up to 12 months.



## NON-SURGICAL WEIGHT LOSS

ORBERA365™ is a reversible minimally invasive weight loss procedure, which means no incisions, stitches, scars, or anatomical modifications.



**500k**

## REAL WORLD RESULTS

Over 500,000 intragastric balloons have been distributed worldwide.<sup>1</sup>



**20**  
years

## A TRUSTED INTRAGASTRIC BALLOON FOR A REASON

Intragastric balloons have helped thousands meet their weight loss goals for over 20 years.

# OPTIMISED BALLOON DESIGN

Key features of ORBERA365™ contribute to its excellent standing and years of success. You can feel confident that your gastric balloon has been designed with your comfort and safety in mind.



## ULTRA SMOOTH AND ROUND

The ORBERA365™ balloon has no protrusions, no sharp edges and no hard surfaces that can irritate your stomach. The innovative ORBERA365™ design offers an incredibly smooth, soft and round shape to put your safety first and which may limit the risk of stomach ulcerations.



## 7+ LAYERS OF HIGH DENSITY SILICONE

Each ORBERA365™ gastric balloon is created with 7+ layers of some of the highest medical-grade silicone for durability, so it can withstand digestive fluids and stomach acid with ease for up to 12 months.



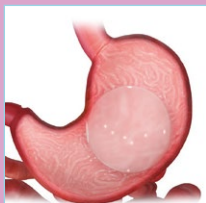
## EFFECTIVE WEIGHT LOSS

ORBERA365™ is designed to support comfortable fullness after meals by taking up space in the stomach, helping you reconnect with your body's natural hunger signals.



## OPTIMAL AND CUSTOMISABLE SIZE

ORBERA365™ can be tailored to your stomach and take up just the right amount of space. At about the shape and size of a grapefruit, each balloon can be filled with as little as 400ml or as much as 700ml, to suit your stomach.



# YOUR QUESTIONS ANSWERED

## DO I QUALIFY FOR ORBERA365™?

To qualify for Orbera365™, you must be an adult, have a body mass index (BMI) greater than 30, have failed to achieve and maintain weight loss with a supervised weight-control programme, and be willing to participate in a medically supervised programme. Your doctor will review your medical history with you to determine if Orbera365™ is right for you.

## WHAT DOES IT FEEL LIKE?

Orbera365™ takes up space in patients' stomachs and helps you feel satisfied with smaller portions. It teaches balanced portion awareness over the 12 months it is implanted.

It typically takes a few days for your body to adjust to the Orbera365™ balloon and you may experience some temporary discomfort, such as nausea, vomiting and reflux, while your body adjusts - your care team will help you manage this.

## DOES IT REALLY WORK? HOW MUCH CAN I EXPECT TO LOSE?

It is important to understand that the balloon is a tool to aid weight loss and must be used in conjunction with diet, exercise, and a behavior modification programme. The amount of weight you lose and maintain will depend on how closely you follow your diet and adopt long-term lifestyle changes. Clinical studies on intragastric balloons have shown that weight loss varies from person to person.

## WHEN WILL I SEE THE RESULTS?

To receive an Orbera365™ balloon you must be willing to follow a 18-month programme. The programme starts with the positioning of the balloon and a healthy diet and exercise regime for 12 months. That is followed by 6 more months of a healthy diet and exercise programme without the balloon in your stomach.

Many people are able to use the time with their ORBERA365™ balloon and coaching to develop a new lifestyle so that they are able to maintain their progress and continue building healthy, sustainable habits. This is why the coaching and follow up after the balloon removal is so important. However, some patients may regain weight after the balloon is removed.



## Important Orbera365™ Intra-gastric Balloon System Safety Information:

- The Orbera365™ Intra-gastric Balloon is made to help you lose weight. From the time that your balloon is placed and for six months after it is removed, you need to follow a healthy diet and exercise program to lose weight. You may not lose weight if you do not follow the program. Your doctor's clinical team, including dietitians, nutritionists and/or exercise trainers, should help you on your weight loss journey.
- The Orbera365™ Intra-gastric Balloon is for adults who are suffering from obesity and have not been able to lose weight and keep it off. To receive an Orbera365™ balloon, you must be willing to follow a 18-month program. The program begins with the use of the balloon and a healthy diet and exercise program for 12 months. That is followed by 6 more months of a healthy diet and exercise program without the balloon in your stomach.
- Your doctor will ask you about your medical history and will also perform a physical examination to determine your eligibility for the device. Additionally, at the time of placement, the doctor may identify internal factors, such as stomach irritation or ulcers, which may prevent you from receiving Orbera365™
- You must not receive Orbera365™ if you are pregnant, a woman planning to become pregnant within six months' time, or breast-feeding.
- You must maintain regular contact with your doctor while the balloon is in your stomach. Nausea and vomiting are common when the balloon is placed. Patients typically adjust to the balloon in the first few weeks, then these symptoms improve. If you adjust to the balloon, but then you begin to feel significant stomach pain, contact your doctor immediately as this may be signs of a significant problem with your stomach and could lead to death.
- Do not use Orbera365™ for more than 12 months. Prolonged balloon placement may increase the risk of the balloon deflating. A deflated balloon can cause the bowels to block, requiring surgery. While it has not yet been reported, it is possible for an unaddressed blockage to cause death.
- Call your doctor if you have any concerns about your health or well-being at any time during the 12-month placement of the balloon.
- For full safety information please visit [www.IFU-BSCI.com](http://www.IFU-BSCI.com) or talk with your doctor.

1. Calculations performed by Boston Scientific. Data on file.
2. Wiggins T, Sharma O, Sarfaraz Y, Fry H, Baker J, Singhal R. Safety and Efficacy of 12-Month Intra-gastric Balloon-Series of over 1100 Patients. *Obes Surg.* Jan 2024;34(1):176-182. doi:10.1007/s11695-023-06953-0
3. Jamal MH, Al-Kanawati N, ElAbd R, et al. A Study Examining the Orbera365 Intra-gastric Balloon Safety and Effects on Weight Loss. *clinical. Obes Surg.* Dec 2021;31(12):5342-5347. doi:10.1007/s11695-021-05729-8

**CAUTION:** The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found at [www.IFU-BSCI.com](http://www.IFU-BSCI.com). Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material is not intended for use in France. 2025 © Boston Scientific Corporation or its affiliates. All rights reserved.

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There are risks associated with all medical procedures. Please talk with your doctor about the risks and benefits associated with Orbera365™.

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