

# A New Weight-loss Option:

# INTRAGASTRIC BALLOONS

by Jaime Ponce, MD, FACS, FASMBS; and Rachel Moore, MD, FACS, FASMBS

**F**or individuals seeking to improve their health, the weight-loss journey may provide too few options in the gap between diet and exercise and bariatric surgery. Now, patients in the U.S. have a new Food and Drug Administration (FDA) approved treatment option requiring no incisions and no overnight stay at a medical facility — intragastric balloons.

## What are Intra-gastric Balloons?

Intra-gastric balloons are soft, yet durable, silicone spheres that take up space in a patient's stomach and help reinforce proper portion control by providing a feeling of being full with less food consumption. Combined with support programs for exercise, diet, nutrition and emotional support, an intra-gastric balloon can kick-start a weight-loss program.

## How is the Procedure Performed?

In a non-surgical procedure, typically done under a mild sedative, an un-inflated intra-gastric balloon is placed into the stomach using an endoscope that is fed into the patient's mouth and down the esophagus. It is then filled with saline (salt water) until it is about the size of a grapefruit. The procedure normally takes about 20 minutes and patients can usually go home the same day. Once the balloon (or balloons) is in place, a 12-month coaching and support program supervised by healthcare experts begins. This team may include dietitians, psychologists and exercise physiologists, among others, to help keep patients motivated and working through weight-loss barriers to meet long-term goals.

## How Does an Intra-gastric Balloon Work?

Intra-gastric balloons occupy existing space in your stomach for six months, serving as built-in portion control so you may feel full and satisfied with less food. They do not change or alter the anatomy of the stomach in any way. After six months, the balloon is removed in the same way it was placed, endoscopically. Through a procedure done under a mild sedative, it is deflated and then removed through the esophagus and mouth.

## Who qualifies for an Intra-gastric Balloon?

Intra-gastric balloons are intended for adult patients who have a Body Mass Index (BMI) of 30-40 kg/m<sup>2</sup>, and who have tried other weight-loss programs but were unable to lose the weight or keep it off. Intra-gastric balloons are also an option for individuals who do not want or do not qualify for bariatric surgery.

## Weighing Your Options

There are two intra-gastric balloons currently approved by the FDA: the ReShape™ Dual Balloon and the ORBERA™ Intra-gastric Balloon. Both devices have a similar procedure for insertion and removal, as well as for consultation.

## Conclusion

Using an intra-gastric balloon is not a cure for obesity, but can be a suitable option for individuals who have tried other weight-loss options that have not shown results, or who either do not qualify or are not interested in bariatric surgery. The procedure, coupled with the 12 months of counseling, provides the support needed to help you change your eating habits and maintain weight-loss long-term. Working hard on these new habits will give you the best chance of losing weight.

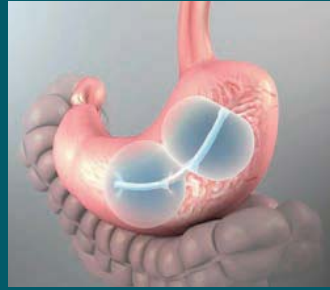
**“Combined with support programs for exercise, diet, nutrition and emotional support, an intra-gastric balloon can kick-start a weight-loss program.”**

# Intragastric Balloon Options

The ORBERA™ Intragastric Balloon is a single balloon that is inserted into the stomach using an endoscope, and is then filled with saline (salt water) until it is about the size of a grapefruit.



The Reshape™ Dual Balloon is two separate silicone balloons with a silicone tube in the middle. The dual balloon device is inserted into the stomach using an endoscope and filled with saline.



While both intragastric balloons are FDA-approved, you should consult with your doctor about any risks or complications, along with the option that is best for you.

## How Effective are Intragastric Balloons?

Both the ORBERA™ Intragastric Balloon and ReShape™ Dual Balloons have run clinical trials to demonstrate their effectiveness in bariatric patients and to determine any possible side effects present from using the device.

A clinical study, called the REDUCE Pivotal Trial, was performed at eight hospitals in the United States. In the study, patients who had the ReShape™ procedure lost 2.3 times as much weight as patients who only received diet and exercise coaching. In a study of the ReShape™ procedure in commercial use in Europe, ReShape™ patients on average lost 32 pounds and maintained 98 percent of their weight-loss within the first year. In the clinical study of 265 patients, the most common side effects of the ReShape™ procedure were vomiting, nausea and abdominal pain. These conditions are to be expected as the stomach gets used to the presence of the balloon, and generally go away after three to five days.

U.S. clinical trial data on the ORBERA™ balloon showed that within six months, the average person lost 3.1 times the amount of weight as compared to diet and exercise alone. In a large European clinical trial, weight-loss averaged over 41 pounds. Once the ORBERA™ balloon was removed, patients maintained 89 percent of the initial weight-loss. Side effects after the ORBERA™ balloon placement included nausea and vomiting in some patients and resolved within 3-4 days. Over 220,000 ORBERA™ balloons have been placed in individuals worldwide with an extremely low rate of complications.

### About the Authors:

*Jaime Ponce, MD, FACS, FASMBS, has been practicing bariatric surgery since 1998 and is the Medical Director for Hamilton Medical Center Bariatric Surgery program in Dalton, Georgia and the Co-director for Memorial Hospital Bariatric Surgery program in Chattanooga, Tenn. Dr. Ponce is past-president (2012-2013) of the American Society for Metabolic and Bariatric Surgery (ASMBS) and is a past-president of the IFSO North American Chapter (2013-2014).*

*Rachel Moore, MD, FACS, FASMBS is in her 13th year of high-volume bariatric surgery practice with a group of six surgeons in New Orleans. Dr. Moore is the founding President of the Louisiana chapter of the American Society for Metabolic and Bariatric Surgery (ASMBS) and is an advocate on the state and national level for improved patient access to obesity treatment. She is currently serving as co-chair of the ASMBS State Chapters Committee and Chair of the Hospitality committee planning Obesity Week 2016 in New Orleans.*



# ABOUT THE OBESITY ACTION COALITION (OAC)

The Obesity Action Coalition (OAC) is a National non-profit organization dedicated to giving a voice to individuals affected by obesity and helping them along their journey toward better health. Our core focuses are to elevate the conversation of weight and its impact on health, improve access to obesity care, provide science-based education on obesity and its treatments, and fight to eliminate weight bias and discrimination.



VIBRANT COMMUNITY



NATIONAL AWARENESS CAMPAIGNS



ANNUAL CONVENTION



ADVOCACY



PUBLIC EDUCATION

## LEARN, CONNECT, ENGAGE

The OAC knows that the journey with weight can be challenging but we also know that great things happen when we learn, connect and engage. That is why the OAC Community exists. Our Community is designed to provide quality education, ongoing support programs, an opportunity to connect, and a place to take action on important issues.

### Through the OAC Community, you can get access to:

- Weight & Health Education • Community Blogs
  - Community Discussion Forum
  - Ongoing Support • Meaningful Connections
- AND MUCH MORE**



**JOIN TODAY: GO TO [OBESITYACTION.ORG/JOIN](http://OBESITYACTION.ORG/JOIN)**

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