

## IMPORTANT ORBERA® INTRAGASTRIC BALLOON SYSTEM SAFETY INFORMATION

The ORBERA® IntraGastric Balloon System is a weight loss aid for adults suffering from obesity, with a body mass index (BMI)  $\geq 30$  and  $\leq 40$  kg/m<sup>2</sup>, who have tried other weight loss programs, such as following supervised diet, exercise, and behavior modification programs, but who were unable to lose weight and keep it off.

To receive ORBERA® you must be willing to also follow a 12-month program, beginning with the placement of ORBERA® and continuing for 6 months after, that includes a healthy diet and exercise plan. If the diet and exercise program is not followed, you will not experience significant weight loss results; in fact, you may not experience any weight loss.

Losing weight and keeping it off is not easy, so you will be supervised throughout this program by a team of physicians, physiologists, and nutritionists. This team will help you make and maintain major changes in your eating and exercise habits.

ORBERA® is placed for no more than six months. Any time that the balloon is in the stomach for longer than six months puts you at risk for complications, such as bowel obstruction, which can be fatal.

Some patients are ineligible to receive ORBERA®. 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 ORBERA®.

You must not receive ORBERA® if you are pregnant, a woman planning to become pregnant within six months' time, or breast-feeding.

Complications that may result from the use of ORBERA® include the risks associated with any endoscopic procedure and those associated with the medications and methods used in this procedure, as well as your ability to tolerate a foreign object placed in your stomach. Possible complications include: partial or complete blockage of the bowel by the balloon, insufficient or no weight loss, adverse health consequences resulting from weight loss, stomach discomfort, continuing nausea