



Closing the Obesity Treatment Gap with the *ReShape*® Integrated Dual Balloon

The United States is experiencing a public health crisis of epidemic proportions: more than one-third (34.9% or 78.6 million) of adults in the U.S. are obese.ⁱ Since the early 1980s, obesity has been increasing, with the number of obese people in the U.S. more than doubling in the following two decades. In June 2013, the American Medical Association officially classified obesity as a disease. Clinically defined as having a Body Mass Index (BMI) of more than 30, obesity can lead to numerous, serious health complications including heart disease, stroke, type 2 diabetes and certain types of cancer. As obesity rates continue to increase, so does the cost to our healthcare system. The estimated annual medical cost of obesity in the U.S. was \$147 billion in 2008, and the medical costs for people who are obese were \$1,429 higher than those of normal weight.

Little progress has been made in the last 20 years to find non-invasive treatment options that can effectively complement sensible eating habits and physical activity to achieve desired and sustainable weight loss. Diet and exercise, weight loss drugs and surgery are the primary treatment options currently available. However, a diet and exercise program is often not enough, and most of the approved weight loss drugs have not met with widespread acceptance, and some have safety concerns. While a small subset of obese patients (those with a BMI of 35 or higher) are candidates for bariatric surgery, many fear the risks associated with this type of permanent procedure. In fact, one study estimates that only one percent of those that qualify for surgery actually go forward with it.ⁱⁱ

Finally, new minimally invasive options are starting to emerge for people with a BMI between 30 and 40 who find themselves in this treatment gap. Recently approved by the U.S. Food and Drug Administration (FDA), the *ReShape* Procedure is a first-of-its-kind, non-surgical weight loss procedure that uses advanced integrated dual balloon technology to help people with mild to moderate obesity lose weight. *ReShape* provides a new option for individuals who haven't succeeded at diet and exercise alone, and do not want or do not qualify for bariatric surgery.

ReShape is a next generation technology with features that are designed to enhance performance in three important areas. First, two connected balloons have a larger fill volume than a typical single balloon. Second, it is designed for greater comfort by mounting the two balloons on a flexible shaft that allows the device to conform to the natural shape of the stomach. Finally, the *ReShape* Integrated Dual Balloon is the only intragastric balloon that incorporates a feature that is designed to mitigate the potential for migration of a deflated balloon from the stomach into the intestines.

The *ReShape* Dual Balloon is placed in the stomach during an outpatient procedure that typically takes 20 minutes using conscious sedation (light anesthesia). An endoscope is inserted through the mouth into the stomach and the un-inflated dual balloon is advanced over a guide wire, and precisely placed in the stomach where it is inflated with saline. The dual balloon occupies existing space in the stomach for six months, serving as built-in portion control so patients may feel full and satisfied with less food. It does not change or alter the natural anatomy of the stomach in any way. During this time and for the six

months after the balloon is removed, *ReShape* patients receive comprehensive counseling and support services that include frequent in-office coaching sessions to encourage new habits and lasting results.

ReShape was evaluated in the REDUCE pivotal trial, the results of which were presented at the 2014 ObesityWeek, the annual meeting of the American Society for Bariatric Surgeons and published in the journal [*Surgery for Obesity and Related Diseases*](#). In that study, patients that had *ReShape* lost 2.3 times as much weight as a control group that received diet and exercise coaching only. There were also measurable and sustained improvements in co-morbidities and strong patient satisfaction with the procedure.

ReShape has also shown to provide clinically significant weight loss in EU commercial use. In a study of *ReShape* in Spain, *ReShape* patients on average lost 47% of their excess weight and maintained 98% of their weight loss at one year.

Today, more than 60 million Americans are believed to be within the BMI range of 30-40, many of whom have struggled with a lack of effective weight loss options. Fortunately, the tide is turning in obesity treatment, and *ReShape* provides a truly unique, next generation treatment option that can deliver sustained results and significant life changes for patients.

i Ogden C. (2012); Prevalence of Obesity in the United States 2009-2010; NCHS Data Brief No. 82

ii Bariatric Surgery as a Highly Effective Intervention for Diabetes: News Flash or Preaching to the Choir? Comments on ‘Obesity, Type 2 Diabetes Mellitus, and Other Comorbidities’”, Jon C. Gould, MD, Arch Surg. 2012

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