



FAQ

What is obesity?

Obesity is a diseaseⁱ that is associated with having an excess of body fat, determined by genetic and environmental factors that are difficult to control when dieting. Obesity is generally defined as having a Body Mass Index (BMI) of 30 or greater.

How many people in the United States are considered obese?

Since the early 1980s, the prevalence of obesity in the U.S. has more than doubled. More than one-third (34.9 percent or 78.6 million) of U.S. adults are obese.ⁱⁱ It is estimated that nearly 35 percent of Americans over the age of 20 are obese,ⁱⁱⁱ and that 41 percent will be obese by 2015.^{iv}

What are the risks of obesity?

Obesity can lead to numerous, serious health complications, including many of which are the leading causes of preventable death, including heart disease, stroke, type 2 diabetes and certain types of cancer.^v

What are the current treatment options for obesity?

Little progress has been made in the past 20 years to find effective, non-invasive methods to help patients lose weight; a significant gap existed in the obesity treatment space between the current options of diet and exercise, weight loss drugs, and more invasive and irreversible interventions such as bariatric surgery. A diet and exercise program is often not enough and most of the approved weight loss drugs have not found widespread acceptance, and may carry safety concerns. Bariatric surgery is usually reserved for patients with a BMI of 35 or higher^{vi}, but many who are eligible do not want 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.^{vii}

As of 2015, new minimally invasive options are starting to emerge for people with a BMI between 30 and 40 who find themselves in this treatment gap.

What is the *ReShape*[®] Procedure?

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. Patients who undergo the *ReShape* Procedure also receive 12 months of comprehensive counseling and support services that include frequent in-office coaching sessions to encourage new habits and lasting results.

Who is a candidate for *ReShape*?

ReShape provides a new option for adults with a BMI of 30-40 and a related health condition who haven't succeeded at diet and exercise alone, and do not want or do not qualify for bariatric surgery.

Many people within the BMI range of 30-40 do not think of themselves as obese, and therefore may not consider themselves candidates for a procedure like *ReShape*. In reality, these patients are technically classified as mild to moderately obese and may be in need of additional tools, beyond diet and exercise alone, to help them lose weight.

What are the benefits of the *ReShape* Dual Balloon technology?

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.

What is the *ReShape* Integrated Dual Balloon made of?

The *ReShape* Balloon is made of acid-resistant silicone and is filled with saline once in the stomach.

How is the *ReShape* Dual Balloon inserted?

The uninflated balloons are placed in the stomach during an outpatient procedure that typically takes 20 minutes using conscious sedation (light anesthesia). While the patient is under sedation, an endoscope is inserted through the mouth into the stomach. The uninflated balloons are advanced over a guide wire and are placed precisely in the stomach. Each balloon is inflated with saline and independently sealed. The procedure is completely non-surgical; there are no incisions, sutures or scars.

How is the *ReShape* Dual Balloon removed?

After six months, the patient returns, and the balloon is removed during a second outpatient endoscopic procedure that typically takes 20 minutes. The balloon is completely drained in a controlled manner. A standard tool is used to securely capture the deflated dual balloon and the device is removed through the mouth.

What coaching services are provided with the *ReShape* Dual Balloon?

During the six months the dual balloon is in place and for the six months after, patients receive nutrition and exercise coaching from allied health professionals at their *ReShape* physician's office. Patients meet with their coaches in person once a month to track their weight loss and discuss their progress.

ReShape also provides patients with access to the *ReShape* Patient Portal. Patients are encouraged to login into the portal daily to track their food intake, exercise and weight loss. The *ReShape*® Patient Portal includes an online support community where patients can interact with each other and provides helpful tips and healthy recipes to help keep patients on track with their weight loss. Coaches have access to the *ReShape* Patient Portal to monitor how the patient is doing in between visits.

Has *ReShape* been studied in a clinical trial?

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](#).

What were the primary endpoints?

There were two primary efficacy endpoints:

1. Comparison of excess weight loss percentage between treatment and control groups
2. Excess weight loss percentage responder rate in the treatment group

How much weight did those in the study group lose on average?

The REDUCE trial demonstrated that patients who underwent the *ReShape* Procedure lost 28%EWL, which is 2.3 times more excess weight at six months – compared to control patients treated with diet and exercise alone who only lost 12%EWL. There were significant and sustained improvements in co-morbidities and strong patient satisfaction, along with maintenance of two-thirds of the weight loss, through 12 months of study follow up. In a subject satisfaction survey from the U.S. clinical trial, 64% of study subjects stated that they would have the *ReShape* Procedure again, and 78% would recommend it to a friend.

Has the procedure been successful outside of the US?

ReShape has been available in Europe since 2011 and has shown clinically significant weight loss in commercial use. In a prospective evaluation of 60 patients conducted in Spain, the *ReShape* Integrated Dual Balloon demonstrated clinically significant weight loss of 47% EWL, a favorable safety profile and high patient satisfaction rate. Additional clinical experience in Spain found that sequential implantation of the dual balloon was safe and not associated with any unanticipated adverse events.

How much does the *ReShape* Procedure cost?

ReShape, which includes the advanced dual balloon technology and 12 months of premium coaching and support, is available on a self-pay basis to patients and cost will vary by healthcare provider and market.

Where is *ReShape* available?

ReShape will be gradually available to patients over the coming months, as physicians and allied health professionals are trained on the procedure and support program to optimize patient outcomes. Patients can sign up for ongoing updates at www.ReShapeReady.com.

Who is *ReShape* Medical, Inc.?

ReShape Medical, Inc. is an FDA regulated medical device company focused on the development and commercialization of its dual intragastric balloon for weight loss. Driven by a passion to address the worldwide obesity epidemic, the company has developed a non-surgical alternative for obese patients seeking treatment. Additional company information can be found at www.pro.ReShapeReady.com.

i <http://www.ama-assn.org/ama/pub/news/news/2013/2013-06-18-new-ama-policies-annual-meeting.page>
ii <http://jama.jamanetwork.com/article.aspx?articleid=1832542>
iii <http://www.cdc.gov/nchs/fastats/overwt.htm>
iv <http://www.reuters.com/article/2007/07/19/idUSN1841918320070719>
v <http://www.cdc.gov/obesity/data/adult.html>
vi NIH/NHLBI, NAASO. The Practical Guide: Identification, Evaluation, and Treatment of Overweight and Obesity in Adults. Bethesda, Md: NIH; 2000
vii *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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