

FDA Approves The ReShape™ Integrated Dual Balloon System, A First-Of-Its-Kind Non-Surgical Weight Loss Procedure For People With Mild To Moderate Obesity

- *Next generation dual balloon designed to create a feeling of fullness while providing patient comfort and safety*

- *Proven to provide more than twice the weight loss of diet and exercise alone*

- *Procedure integrated with 12 months of medically-supervised nutrition and exercise coaching to help enable sustained weight loss*

SAN CLEMENTE, Calif., July 28, 2015 /PRNewswire/ -- *ReShape Medical*® today announced that the U.S. Food and Drug Administration (FDA) has approved the *ReShape*™ Integrated Dual Balloon System, a first-of-its-kind non-surgical weight loss procedure for people with mild to moderate obesity. The *ReShape* Procedure 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.

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"Many Americans who face the risk and consequences of obesity have struggled with a lack of effective weight loss options when their BMI is in the 30-40 range," said John Morton, MD, MPH, President of the American Society for Metabolic and Bariatric Surgery. "Options like *ReShape* address a significant gap that exists between diet and exercise, weight loss medications and surgery, offering a minimally invasive, reversible option which we hope will promote long-term healthy habits."

The dual balloon is inserted in the stomach endoscopically and filled with saline. It does not change or alter the natural anatomy in any way and remains in the stomach for six months. 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.

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 is designed to mitigate the potential for migration of a deflated balloon from the stomach into the intestines.

"While intragastric balloons have been used successfully outside of the U.S. for many years, there has been little design improvement or innovation of this treatment," said Rick Thompson, President and CEO of *ReShape Medical*. "We looked closely at previous balloons when designing our dual balloon and we feel confident that our unique, next-generation design will help to deliver sustained results and significant life changes for patients."

The *ReShape* Integrated Dual Balloon System 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 Metabolic and Bariatric Surgery and published in the journal [Surgery for Obesity and Related Diseases](#). In that study, patients that had the *ReShape* Procedure 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. In a study of the *ReShape* Procedure in commercial use in Europe, *ReShape* patients on average lost 47% of their excess weight and maintained 98% of their weight loss at one year.

"Through clinical studies in the U.S and abroad, *ReShape* has now been used by hundreds of patients," said Jaime Ponce, MD, lead investigator on the REDUCE trial. "Positive data from the rigorously designed pivotal study, coupled with commercial experience in Europe, demonstrate that *ReShape* can provide an important new non-surgical option to help patients in the U.S. lose weight and give them the tools needed to keep it off."

The company plans to make the *ReShape* Procedure available to patients first in select markets, as physicians and allied health professionals are trained on the procedure and support program to optimize patient outcomes. The *ReShape* Procedure, including the 12 months of premium coaching and support, will be available on a self-pay basis and price will vary by healthcare provider and market. Ongoing updates about the availability of the *ReShape* Procedure can be found at www.ReShapeReady.com/get-started.

Additional commentary:

"Anyone who has struggled with diet and exercise to lose weight knows it can be a very frustrating cycle. Still, the idea of undergoing surgery or being on medication for life is also unattractive," said Carmelia, a *ReShape* patient. "The ability to make long-term changes in my lifestyle with *ReShape* has not only changed how I see myself in the mirror, but how I see my future."

"In the past, bariatric surgeons have had few options to offer patients who did not qualify for bariatric surgery," said Ninh Nguyen, MD, Past President of the American Society for Metabolic and Bariatric Surgery. "The approval of *ReShape* opens up a new opportunity for these patients or patients who are not ready for surgery, by providing an effective nonsurgical treatment to help them with their weight loss and a path to a healthier lifestyle."

About *ReShape Medical*®

ReShape Medical is a 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. The *ReShape* device has been available in the European Union since December 2011.

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