

ReShape® B-Roll Script

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 <p>ReShape Medical® Receives FDA Approval for Non-Surgical Weight Loss Device</p> <p>Video Provided by: ReShape Medical®</p> <p>Contact: MSLGROUP reshapemedical@mslgroup.com 781-684-0770</p>	
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 <p>Medical Professionals</p>	
<p>Brooke Henson, RN, BSN, CBN Bariatric Surgery Clinical Coordinator Chattanooga Bariatrics</p>	
	<p>HENSON: I think the biggest barriers to weight loss really are the American lifestyle. I think we're all working long hours, have long days, don't have time for sit-down dinners. We have fast food. A lack of activity and exercise. Our jobs are sedentary. And it really impacts our weight.</p>
	<p>HENSON: The <i>ReShape</i> Procedure is different from other weight loss procedures because it's a non-surgical option for patients. It really gives them a low-risk alternative for weight loss for those patients who aren't ready for other means, especially for surgery.</p>
	<p>HENSON: A candidate for the <i>ReShape</i> Procedure is someone who has tried multiple attempts at weight loss in the past. Some have been successful, some have not. This patient's motivated. They're ready to move forward with weight loss. But they're not ready to take the step towards surgery.</p>
	<p>HENSON: Patients are really excited about the extra components with the <i>ReShape</i> balloon. They like to know they're going to have that psychological support, they're going to have the nutritional guidance. It's not just getting your procedure and then being on their own. They really like the team approach to the weight loss.</p>

	<p>HENSON: We give our patients lots of different tools in order to be successful with their weight loss efforts. One of those tools is the patient portal. It allows patients to go in and have that accountability with their food and diet choices, with their exercise with their water intake. It also just forms a community between the patients.</p>
	<p>HENSON: This is a 12 month program where we see the patients on a monthly basis. The balloon stays for six months, so we're seeing the patient each month, and then also we see them for the six months following balloon removal to continue to work on and reinforce the progress that they've made and the lifestyle changes that they've been able to adapt.</p>
	<p>HENSON: I think counseling is extremely important in weight loss. And I look at it as the instruction guide. You can have a tool, but if you don't know how to use it, you're not going to be as successful with it. And that counseling really enables the patients the fundamental tools and instructions that they need to be successful with their weight loss.</p>
	<p>HENSON: So the <i>ReShape</i> balloon is really the jumpstart to positive change. So the quick weight loss that a patient is able to achieve, along with the lessons learned through the dietary and exercise counseling really enables the patients to have long-term success.</p>
	<p>HENSON: The stories I love most hearing from patients are the positive change it's made in their everyday life, whether it's being able to play longer periods of time with their children, whether it's being able to be with friends and family, be in a comfortable setting, and not be so socially isolated because of their weight. Those daily impacts that patients experience, they may be the small things, but those small things make such a big difference.</p>
<p>Jaime Ponce, MD, FACS Bariatric Surgeon Hamilton Medical Center</p>	<p>PONCE: So in the United States, obesity is a big issue. Over the last 20 to 30 years, the number of obese adults continue to increase. And over the last 40 years it's been estimated that the number of obese adults has doubled in size. Right now, today, about one third of the population of the United States is considered obese. And about two thirds of the population are considered overweight or obese. So it's a significant proportion of the population that has this problem.</p>
	<p>PONCE: Obesity comes associated with different medical risks. You know, it's a long list of about 30 different medical conditions that are associated to being overweight. The most common ones and the ones that everybody hears about is type two diabetes, hypertension, sleep apnea. But there are many more, like bone and joint disease, gastroesophageal reflux disease.</p> <p>It is well known that people that suffer from obesity, when they lose weight, many of these problems improve.</p>
	<p>PONCE: The biggest problem that we have is on those patients in-between. You know, the ones that are already past the overweight stage, they're obese, but they're not severely obese to be candidates for surgery.</p> <p>And so I think that's a gap that we have, and that's a gap that probably the intragastric balloon, in this case the <i>ReShape</i> balloon, can fill this gap by giving another option for these patients to get integrated into a good program. With the balloon it's been proven that they can lose more weight and probably achieve better results.</p>

	<p>PONCE: So the <i>ReShape</i> balloon is a device that basically consists of two spheres, balloons that are filled with saline solution and are being placed endoscopically with a scope through the mouth all the way down into the stomach. It's a very easy system.</p>
	<p>PONCE: This balloon allows the patients to have a sensation of fullness in the stomach. And that balloon, integrated into a comprehensive program that has a good diet plan, that has a good counseling and exercise and lifestyle changes, allows these patients to do much better than if they just go through that program without the balloon.</p>
	<p>PONCE: So the <i>ReShape</i> balloon helps patients lose weight because it gives them an additional way of feeling full faster. The balloon is basically occupying the space in the stomach, and it's making patients not have a lot of more space to eat a large portion of food. And so when patients are trying to eat a portion, they have to eat very slowly, they have to chew their food very well.</p>
	<p>PONCE: So the ideal candidate for a <i>ReShape</i> balloon is that patient that is somewhere with a BMI in between 30 to 40 that has already tried to lose weight before and has maximized some of the medical options to lose weight, but is not quite ready for surgery.</p>
	<p>PONCE: The <i>ReShape</i> balloon is not intended to be compared with surgery. And it's not intended to compete with surgery. It's a very different therapy. Surgeries are more permanent therapy that you use for patients that are already struggling with morbid obesity, which is the most severe degree of obesity.</p>
	<p>PONCE: <i>ReShape</i> balloon is intended to be a temporary device that allows patients to engage in a medical weight loss program and have better results than what they traditionally do with a simple diet and exercise. And it is temporary because the balloon has to be removed. It's not intended to be permanent. But it does allow patients to get engaged into the program and the instruction to make some changes for the future.</p>
	<p>PONCE: The most important factor here is how they improve their medical condition. They say, you know, my knees don't hurt as much, you know, I can walk much easier. I don't get short breath when I go up steps, I can get in and out of the car much easier, I can cross my legs, I can go to an amusement park with my grandkids, and being able to get into the rides with them as opposed to not being able to do it. So medical benefits are impressive. Quality of life is impressive. And certainly every time that you improve the health of somebody, you're probably improving the lifespan.</p>
	<p>PONCE: So the Reduce pivotal trial is a trial that was done in the United States, include 326 patients out of eight centers. One group that have the balloon plus diet and exercise, and one group that only had diet and exercise.</p> <p>And there was a significant difference showing, favoring the group that had the balloon. The group that had the balloon had 2.2 times better weight loss than the group that didn't have the balloon. In terms of numbers, you know, the group that had the balloon had close to 28% excess weight loss, compared to about 12% excess weight loss with the group that didn't have the balloon.</p>

	<p>PONCE: The patients that had the balloon, after six months they were followed for another six months without the balloon, and they were able to maintain 65% of the weight that they lost during those six months.</p>
<p>Erik Wilson, MD Division Chief of Elective Surgery and Bariatric Surgery University of Texas Health Science Center at Houston</p>	
	<p>WILSON: The challenges with treating patients with obesity today are mainly tied to access to treatment options. Patients are generally stuck looking for things on their own and dealing with standard medical therapies or their own behavior therapies through what they see on TV or what they hear about from their friends, and there's just not a lot of interventions that are available to the average person that's obese to help them with their weight. Bariatric surgery is an option, but a lot of patients aren't comfortable with a surgical procedure for weight loss. So there's a big gap between medical treatment and surgery that needs to be filled.</p>
 <p>Non-Surgical Weight Loss Procedure</p> <p>Patients</p>	
<p>Carmelia Ashford <i>ReShape</i>® Clinical Trial Patient</p>	
	<p>ASHFORD: The, the procedure was very quick, and I would say two or three hours afterward, I was back to feeling normal.</p>
	<p>ASHFORD: Oh, I was very excited and happy to see the weight coming off, and that motivated me even more to try harder to watch my diet, to pump up my exercise so that I could even lose more.</p>
	<p>ASHFORD: Oh, it was very important to have the support of the staff. You know, number one it kept me accountable. You know, I knew, OK, next week I have to weigh myself when I come into the office. And I didn't want to disappoint the staff nor myself, you know, by gaining weight and going up instead of down.</p>
	<p>ASHFORD: After the procedure, the counseling was just so helpful. I mean, it helped me stay on track, it helped me to stay accountable. It was informative, motivating, it was just great. I think the combination of the procedure and the counseling was really what kept me on track after the procedure.</p>
	<p>ASHFORD: Oh, I would definitely recommend <i>ReShape</i> to people struggling with their weight, because it's an easy procedure, it's, and it definitely works. So that's the main thing. It works.</p>
<p>Kellie Guinn <i>ReShape</i>® Clinical Trial Patient</p>	
	<p>GUINN: I know how it feels to be overweight and how it feels to have people look at you and say, you know, all you got to do is walk, or all you need to do is</p>

	stop eating so much. Well, that's not all you have to do. You have to do a combination of a lot of things.
	GUINN: I was attracted to the <i>ReShape</i> Procedure because it's a minimally invasive procedure and there's no incisions. You're in and out. And then, in six months, the balloons come out of your body, so it's not something that's permanently inside of you.
	GUINN: For the <i>ReShape</i> Procedure, they put me under conscious sedation. The procedure just took approximately 20 to 30 minutes, and when I woke up, I didn't, I couldn't feel any pain.
	GUINN: One of the main benefits, in my opinion, of the <i>ReShape</i> Procedure is the fact that you can choose anything that you normally would have eaten. The thing is, you're not going to want to eat as much because you feel full almost immediately.
	GUINN: The <i>ReShape</i> Procedure really supported me through the whole entire process by teaching me through the diet counseling and the exercise counseling the things that I needed to be doing. And I was able to put those things into practice and bounce them off of somebody else, and show them what I had done that week or the weeks before and receive feedback. And just doing that every month for 12 months really helped me to make the change.
	GUINN: You've got to be active. And part of that cycle, you're tired, but you have to get up and move and then you won't be as tired. When you're thinking about that, that doesn't make a lot of sense until you do it. And then, you're like uh, I didn't know that I had to use energy to have energy.
	GUINN: After the <i>ReShape</i> Procedure, I have more energy. My blood pressure is within the normal range, and I have a really good self-esteem now.
	GUINN: Before the <i>ReShape</i> Procedure, I was a size 18 and after the <i>ReShape</i> Procedure I was in a size eight.
	GUINN: The <i>ReShape</i> Procedure changed my everyday life by allowing me to have more energy, and by showing me that to have energy, I needed to move and exercise. And that has made all the difference in the world. Because I no longer come home and go directly to bed. I no longer sleep as long as I can in the morning. I get up. I'm ready to go. I want to have some fun.
	GUINN: I'm not ashamed of how I look anymore. I don't have a problem buying clothes. Swimsuits, I'll probably always have a problem with, but regular clothing, I can just usually choose something in my size and I'm OK with it. I'm not all torn up about how I look, like I was in the past.
	GUINN: <i>ReShape</i> worked so much better for me than other diets just because of the lifestyle change, and the counseling and the bonds that you build with the people that are counseling you.
	GUINN: Now I know to pay attention to my body's signals and I eat smaller portions, and I know when I'm full.
 <p>ReShape™ Non-Surgical Weight Loss Procedure</p> <p>Company Executives</p>	
<p>Richard Thompson CEO <i>ReShape Medical</i>®</p>	

	THOMPSON: <i>ReShape Medical</i> is dedicated to providing nonsurgical options for the millions of people who are struggling to lose weight.
	THOMPSON: The dual balloon is designed to do three things. First, with two balloons, you can fill more volume in the stomach, causing patients to eat even smaller meals. Second, two balloons fit more comfortably in the natural shape of the stomach. And third, with two balloons, should one accidentally deflate, the second will remain in the stomach, preventing migration into the intestines.
	THOMPSON: With the <i>ReShape</i> Procedure, for the first time, patients with a BMI between 30 and 40 will have a temporary nonsurgical procedure that can help them change their eating habits for the long term.
	THOMPSON: What makes the <i>ReShape</i> Procedure different is that it's a comprehensive program that includes the balloon, but also includes 12 months of patient counseling on diet, exercise and behavior modification that will lead to long term weight loss and success for the patient.
	THOMPSON: In the studies that we've conducted on the <i>ReShape</i> Procedure, both in the United States and abroad, we've measured patient satisfaction and quality of life and have found both to be very high.
John Lehmann, MD, MPH Chief Medical Officer <i>ReShape Medical</i> ®	
	LEHMANN: The biggest unmet need in obesity treatment is the gap between diet and drugs on one side and bariatric surgery on the other.
	LEHMANN: During the <i>ReShape</i> Procedure, the patient is sedated and the doctor places an endoscope into the stomach. Then the device is inserted into the stomach and inflated with saline, and the endoscope is removed.
	LEHMANN: After six months of treatment, the patient is once again sedated and the doctor places the endoscope in the stomach. The fluid is aspirated from both balloons, and then the device is withdrawn from the patient's body.
	LEHMANN: If one balloon deflates, the device remains in the stomach because the second balloon is there to hold it, whereas single balloons, when they deflate, can migrate into the intestines and cause blockage requiring surgical correction.
	LEHMANN: The <i>ReShape</i> Procedure is 12 months of treatment. It starts with six months of balloon treatment to help the patient lose more weight than they've ever lost on diet and exercise, and also to learn how to eat small portions. After the six month period with the balloon, the balloon is retrieved and the patient gets six more months of intensive counseling and support so that they can consolidate all that they've learned with the balloon.
	LEHMANN: We showed that subjects treated with the <i>ReShape</i> balloon lost over twice as much weight as patients who were only treated with diet and exercise.



 <p>Non-Surgical Weight Loss Procedure</p> <p>B-Roll Footage</p>	
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