ReShape™ Integrated Dual Balloon System Instructions for Use

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

DEVICE DESCRIPTION

The *ReShape*™ Integrated Dual Balloon System is a temporary implant designed to facilitate weight loss by occupying space in the stomach. The implant consists of two independently inflated, non-communicating, silicone balloons tethered to a central silicone shaft. It is inserted transorally down the esophagus into the stomach, with endoscopic guidance via a delivery catheter. When inflated, the *ReShape* Integrated Dual Balloon is designed to occupy a significant portion of the stomach while conforming to the natural shape of the patient's anatomy (see Figure 1). The device's flexible dual balloon design is intended to improve patient comfort while reducing the risk of device migration into the intestine. The maximum placement period for the *ReShape* Dual Balloon is 6 months, and it must be removed at that time or earlier. At the conclusion of treatment, the *ReShape* Dual Balloon is aspirated using the *ReShape* Removal Catheter and removed endoscopically.

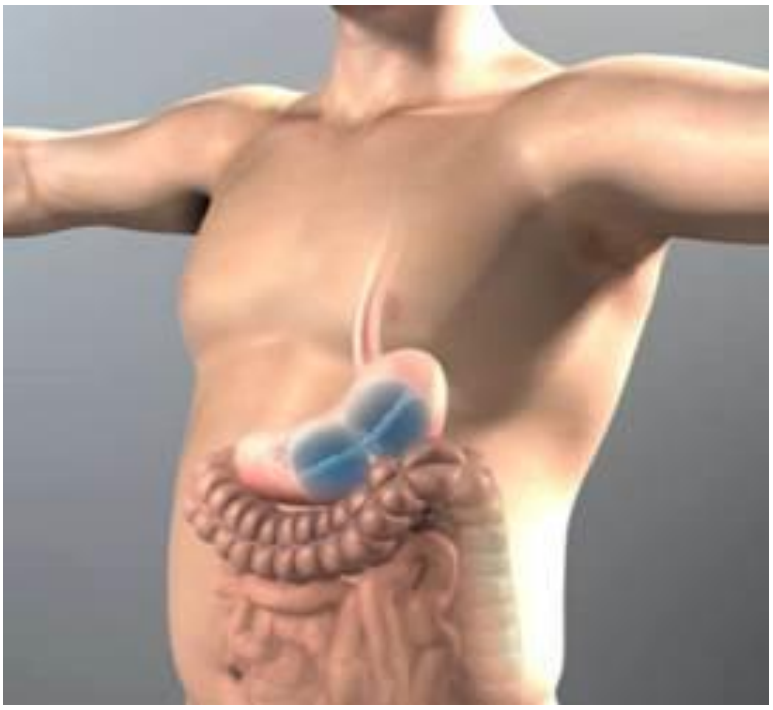
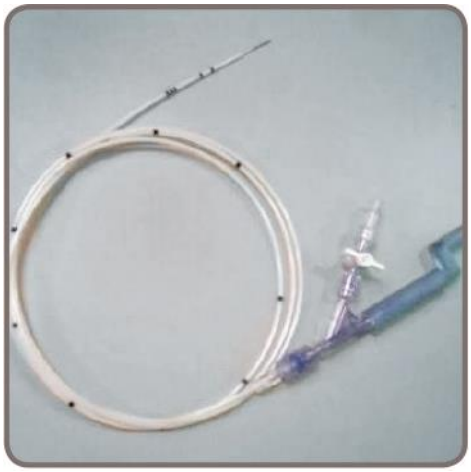


Figure 1. *ReShape* Dual Balloon in the Stomach

The *ReShape* Integrated Dual Balloon System consists of the following components:

***ReShape* Dual Balloon and Delivery Catheter**

***ReShape* Removal Catheter** (packaged separately)



***ReShape* Guidewire**

***ReShape* Valve Sealant** (packaged separately)

INDICATIONS FOR USE

The *ReShape* Integrated Dual Balloon System is indicated for weight reduction when used in conjunction with diet and exercise, in obese patients with a Body Mass Index (BMI) of 30 – 40 kg/m^2 and one or more obesity-related comorbid conditions. It is indicated for use in adult patients who have failed weight reduction with diet and exercise alone.

CONTRAINDICATIONS

- Prior gastrointestinal surgery with sequelae, i.e. obstruction, and/or adhesive peritonitis or known abdominal adhesions.
- Prior open or laparoscopic bariatric surgery.
- Any inflammatory disease of the gastrointestinal tract including esophagitis, gastric ulceration, duodenal ulceration, cancer or specific inflammation such as Crohn's disease.
- Potential upper gastrointestinal bleeding conditions such as esophageal or gastric varices, congenital or acquired intestinal telangiectasis, or other congenital anomalies of the gastrointestinal tract such as atresias or stenoses.
- A gastric mass.
- A hiatal hernia > 5 cm or ≤ 5 cm with associated severe or intractable gastro-esophageal reflux symptoms.
- A structural abnormality in the esophagus or pharynx such as a stricture or diverticulum that could impede passage of the delivery catheter and/or an endoscope.
- Achalasia or any other severe esophageal motility disorder that may pose a safety risk during the removal of the device
- Severe coagulopathy
- Hepatic insufficiency or cirrhosis
- Serious or uncontrolled psychiatric illness or disorder that could compromise patient understanding of or compliance with follow up visits and removal of the device after 6 months.
- Alcoholism or drug addiction.
- Patients unwilling to participate in an established medically-supervised diet and behavior modification program, with routine medical follow-up.
- Patients receiving daily prescribed treatment with aspirin, anti-inflammatory agents, anticoagulants or other gastric irritants.
- Patients who are unable or unwilling to take prescribed proton pump inhibitor medication for the duration of the device implant.
- Patients who are known to have, or suspected to have, an allergic reaction to materials contained in the system.
- Patients who have ever developed a serotonin syndrome and are currently taking any drug known to affect the levels of serotonin in the body [e.g., selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), monoamine oxidase inhibitors (MAOIs)] should not undergo placement of the device.
- Patients who are pregnant or breast-feeding.

WARNINGS

- Intestinal obstructions have been reported due to deflated balloons passing into the intestines and have required surgical removal. Death due to intestinal obstruction is possible and has been reported with other intragastric balloons. Patients experiencing any symptoms of an intestinal obstruction (e.g., acute onset of abdominal pain, nausea or vomiting) should be counseled to seek immediate care.
- The maximum placement period for the *ReShape* Dual Balloon is 6 months. The risk of intragastric balloon deflation and intestinal obstruction (and therefore possible complications related to intestinal obstruction) is significantly higher when balloons are left in place longer than 6 months.
- Patients with known abdominal adhesions or who have had prior abdominal surgery or have any signs or symptoms of a bowel obstruction should be carefully evaluated prior to use of the *ReShape* Dual Balloon in relation to possible intestinal obstruction should the device deflate or pass into the intestines. The risk of intestinal obstruction may be higher in patients who have had prior abdominal surgery.

- The *ReShape*™ Valve Sealant is necessary to seal the device valves and prevent balloon leakage. Failure to use the specified amount of Valve Sealant will result in balloon leakage and deflation, and increase the risk of intestinal obstruction (and therefore possible complications related to intestinal obstruction).
- The presence of blue-green urine or sudden loss of satiety, increased hunger and/or weight gain may be a sign of balloon deflation. Patients should be instructed to immediately contact their physician if they observe any of these signs. Clinical means of assessing possible deflation include abdominal ultrasound, barium swallow and endoscopy.
- Patients may not observe or report the presence of blue-green urine following a balloon deflation. Patients should be counseled to seek immediate care if any symptoms of an intestinal obstruction such as acute abdominal pain, nausea or vomiting develop.
- Partially (i.e., one balloon) or fully (i.e., both balloons) deflated devices must be removed promptly. The risk of intestinal obstruction (and therefore possible complications related to intestinal obstruction) is significantly higher when deflated devices are not removed promptly.
- Failure of patients to take prescribed daily proton-pump inhibitor medication increases the risk of gastric ulceration or perforation.
- Using direct endoscopic visualization, confirm proper positioning of the uninflated balloons in the stomach prior to inflation. Failure to do so may cause injury to the esophagus, pylorus or duodenum.
- Patients receiving serotonergic drugs including SSRIs, SNRIs, MAOIs and other prescription and over-the-counter drugs should be cautioned about the possibility of developing serotonin syndrome because of the combination of these medications and the release of methylene blue (in the event of balloon rupture). Patients should immediately seek medical attention if they develop any symptoms of confusion, headache, nausea and vomiting, rapid heart rate, or severe sweating. Serotonin syndrome has been reported in patients given serotonergic psychiatric medications and methylene blue via intravenous administration of methylene blue at doses ranging from 1 mg/kg to 8 mg/kg.
- In the event of balloon rupture, methylene blue would be released into the stomach and absorbed into the circulation. Methylene blue is a drug with multiple pharmacological indications. Methylene blue is a DNA binding agent that tests positive for mutagenicity and DNA damage in bacteria, yeast, mammalian cells, and human tissue obtained after clinical exposures. The internal release of methylene blue would result in a local concentration that is higher than that delivered by the usual IV injection route. The consequences of transient acute methylene blue exposure following balloon rupture are not known.
- Patients should immediately notify their doctor if they become pregnant while the device is in place, as there is a risk for release of methylene blue and birth defects (in the event of balloon rupture). An association exists between the use of methylene blue in amniocentesis and birth defects.

PRECAUTIONS

- It is the responsibility of the physician to advise the patient of known risks and complications associated with the procedure and the device.
- It is the responsibility of the physician to advise the patient of the potential need to remove the device in less than 6 months due to balloon deflation or GI intolerance.
- It is the responsibility of the physician to advise the patient that the maximum placement period for the *ReShape* Dual Balloon is 6 months and it must be removed at that time or earlier.
- Patients must be counseled on the need for proper dietary and exercise habits. Failure to adhere to prescribed dietary and exercise instructions may result in failure to lose weight.
- Insertion and removal of the *ReShape* Dual Balloon should only be performed by physicians experienced in diagnostic and therapeutic endoscopy procedures.
- Each patient must be monitored closely during the entire term of treatment in order to detect the development of possible complications. Each patient should be instructed regarding signs and symptoms of balloon deflation, gastrointestinal obstruction, ulceration and other complications which might occur, and should be advised to contact his/her physician immediately upon the onset of such signs and symptoms.

- It is recommended that patients with a history of documented peptic ulcer associated with *H. pylori* be tested for *H. pylori* and, if found to have a positive test, be treated in accordance with the standard of care prior to dual balloon insertion.
- Ensure that the patient has followed the recommended pre-procedure diet instructions so that no food or liquid is present in the stomach at the time of the insertion or removal procedure:
    - 48 hours prior to the procedure: Soft food only, no meat in any form
    - 24 hours prior to the procedure: Clear liquids only
    - 12 hours prior to the procedure: No food or liquids by mouth
- If food or liquid is present in the stomach at the time of the procedure, it is recommended that the procedure be delayed until a later time. If this is not possible, endotracheal intubation of the patient is recommended to reduce the risk of aspiration.
- Keep the endoscope tip at least 2-3 cm proximal to the delivery catheter detent while disengaging the balloon and removing the catheter. The combined diameter of the catheter detent and the endoscope side-by-side may cause esophageal injury.
- In the event of an emergency removal by a physician untrained in the procedure, endotracheal intubation of the patient is recommended to reduce the risk of aspiration.
- During removal, a laryngoscope and Magill forceps should be available in the event the balloon slips off of the snare and must be retrieved with forceps.
- The confirmation of ulcer healing in patients with ulcers at the time of device removal was not evaluated endoscopically during the REDUCE Pivotal Trial.
- Subjects who are found at retrieval endoscopy to have a gastric ulcer should be placed on 6 – 8 weeks of therapeutic proton pump inhibitor (PPI) medication and followed closely. After completing 6 – 8 weeks of PPI treatment, subjects experiencing potential ulcer symptoms or signs such as abdominal pain or discomfort, dyspepsia, anemia or dark stools should be considered for endoscopic examination to assess ulcer resolution.
- The *ReShape* Dual Balloon is composed of soft silicone elastomer and is easily damaged by instruments or sharp objects. The balloon must be handled only with gloved hands and with the instruments recommended in the Instructions for Use.

It is important to discuss all possible complications and adverse events with the patient. Complications that may result from use of this product include those associated with general endoscopy procedures, those associated with the *ReShape* Dual Balloon specifically and those associated with the patient's degree of intolerance to an implanted foreign body.

Potential risks associated with an endoscopic procedure and sedation include adverse reaction to sedation (headache, muscle pain, nausea), anaphylaxis, cardiac arrest, death, hypoxia, myocardial infarction, perforation, infection, pneumonia, and respiratory distress.

Potential risks associated with the *ReShape* Dual Balloon include ulceration, perforation, significant gastric bleeding, need for blood transfusions, emergency endoscopic therapeutic intervention, abdominal pain, abdominal spasms, nausea, vomiting, bloating, belching, heartburn, dysphagia, dehydration, and sore throat. These complications may be severe enough to require early removal of the *ReShape* Dual Balloon. Although the *ReShape* Dual Balloon design provides an anti-migration feature, there is the potential risk of device migration and intestinal obstruction. The risk of intestinal obstruction is increased if the device is not removed after 6 months. If intestinal migration occurs, the device may pass through the intestine and be passed with stool. However, surgical or endoscopic removal may be required. Death due to intestinal obstruction is possible and has been reported with other intragastric balloons.

Additional risks associated with the *ReShape* Dual Balloon include adverse events related to weight loss and balloon deflation with subsequent early removal. A potential outcome of use of the *ReShape* Dual Balloon is insufficient or no weight loss.

CLINICAL STUDY DESIGN

The REDUCE Pivotal Trial was a prospective, sham-controlled, double-blinded, randomized multicenter clinical study that enrolled 326 obese subjects. Enrolled subjects had an initial BMI of 30 – 40 and at least one obesity-related comorbidity. The Treatment Group (N=187) received the *ReShape* Dual Balloon device plus diet and exercise for 24 weeks, and the Control Group (N=139) received diet and exercise alone. Treatment group subjects had the device removed after 24 weeks and continued with diet and exercise counseling for an additional 24 weeks. Control group subjects who completed the initial 24 weeks and still met the study eligibility criteria were given the option to receive a *ReShape* Dual Balloon device and continued diet and exercise counseling for the 24 week implant period. Safety data from the trial is based on a combination of the 187 treatment subjects randomized to receive the device and 78 control subjects who opted to receive a balloon at 24 weeks (N=265).

ADVERSE EVENTS

Twenty (20) subjects had a total of 31 device- or procedure-related SAEs. The proportion of Dual Balloon-attempted study subjects with any device or procedure-related SAE was 7.5% (20/265, 95% CI 4.2, 10.9%). There were no deaths, no device migrations out of the stomach and no intestinal obstructions. The 31 SAEs were as follows:

Table 1 - Device or Procedure-Related Serious Adverse Events

	Treatment Subjects N=265			
Serious Adverse Events by MedDRA Categorization	**# of events**	**Subjects % (n)**	**Day of Onset* Mean, Median (Min, Max)**	**Device Removed Due to SAE # Subjects (%Subjects)**
Vomiting	12	4.5% (12)	0,0 (0,0)	1/12 (8.3%)
Abdominal pain	6	2.3% (6)	20, 0 (0-118)	2/6 (33.3%)
Gastric ulcer	2	0.8% (2)	58, 58 (19-97)	2/2 (100%)
Epigastric pain	2	0.8% (2)	1,1 (0-1)	0/2 (0.0%)
Nausea	1	0.4% (1)	0	0/1 (0.0%)
Contained esophageal perforation	1	0.4% (1)	168	0/1 (0.0%)
Esophageal tear	1	0.4% (1)	9	0/1 (0.0%)
Upper gastrointestinal hemorrhage	1	0.4% (1)	17	1/1 (100%)
Epigastric discomfort	1	0.4% (1)	97	1/1 (100%)
Pneumonia	1	0.4% (1)	15	0/1 (0.0%)
Muscle pain	1	0.4% (1)	132	0/1 (0.0%)
Emesis with dehydration	1	0.4% (1)	0	0/1 (0.0%)
Dehydration	1	0.4% (1)	120	1/1 (100%)

MedDRA = Medical Dictionary for Regulatory Activities, SAE = serious adverse event
Serious Adverse Event (SAE): any adverse event resulting in death; any adverse event which is life-threatening; any adverse event resulting in hospitalization, or significant prolongation of an existing hospitalization; any adverse event resulting in a persistent, significant impairment; any adverse event requiring significant medical or surgical intervention to prevent a significant impairment; any adverse event resulting in a congenital anomaly or birth defect
*Day of onset measured from initial procedure day

Table 2 - GI System Device-Related Adverse Events Occurring in 10% or More of Subjects

Device-Related Adverse Event (MedDRA Preferred Term)	#Subjects % Subjects (N=264)	Day of Onset	Duration (in days)	Severity Break Down # Subjects (% Subjects)	# Subjects (%Subjects) with AEs onset day ≤ Day 3 post insertion	# Subjects (% Subjects) with AEs onset day ≤ Day 3 post insertion and duration >14 days	# Subjects (% Subjects) with AEs onset day ≤ Day 3 post insertion and duration > 30 days
Vomiting	229 86.7%	Median: 0 Mean: 6.4 Range: 0-168	Median: 3 Mean: 7.3 Range: 0-84	Mild: 143/229 (62.4%) Moderate: 90/229 (39.3%) Severe: 5/229 (2.2%)	226/229 (98.7%)	24/229 (10.5%)	13/229 (5.7%)
Nausea	161 61.0%	Median: 0 Mean: 10.1 Range: 0-175	Median: 7 Mean: 24.9 Range: 0-190	Mild: 120/161 (74.5%) Moderate: 44/161 (27.3%) Severe: 1/161 (0.6%)	14/1615 (90.1%)	38/161 (23.6%)	27/161 (16.8%)
Abdominal pain	144 54.5%	Median: 1 Mean: 26.3 Range: 0-175	Median: 12 Mean: 34.8 Range: 0-194	Mild: 107/144 (74.3%) Moderate: 47/144 (32.6%) Severe: 3/144 (2.1%)	116/144 (80.6%)	48/144 (33.3%)	29/144 (20.1%)
Dyspepsia	47 17.8%	Median: 1 Mean: 24.9 Range: 0-161	Median: 15 Mean: 32.6 Range: 0-174	Mild: 41/47 (87.2%) Moderate: 6/47 (12.8%) Severe: 0/47 (0.0%)	32/47 (68.1%)	14/47 (29.8%)	5/47 (10.6%)
Eructation	44 16.7%	Median: 11.5 Mean: 34.1 Range: 0-134	Median: 90.5 Mean: 88.8 Range: 2-200	Mild: 44/44 (100.0%) Moderate: 0/44 (0.0%) Severe: 0/44 (0.0%)	17/44 (38.6%)	14/44 (31.8%)	14/44 (31.8%)
Abdominal discomfort	35 13.3%	Median: 2.5 Mean: 29.1 Range: 0-142	Median: 25 Mean: 31.6 Range: 2-115	Mild: 28/35 (80.0%) Moderate: 8/35 (22.9%) Severe: 0/35 (0.0%)	21/35 (60.0%)	8/35 (22.9%)	7/35 (20.0%)
Abdominal distension	29 11.0%	Median: 18 Mean: 41.1 Range: 0-140	Median: 29.5 Mean: 41.4 Range: 2-144	Mild: 26/29 (89.7%) Moderate: 2/29 (6.9%) Severe: 1/29 (3.4%)	8/29 (27.6%)	3/29 (10.3%)	2/29 (6.9%)
Gastric ulcer	11 10.3%*	Median: 167 Mean: 128.9 Range: 9-182	Median: 33.0 Mean: 39.9 Range: 11-81	Mild: 9/11 (81.8%) Moderate: 1/11 (9.1%) Severe: 1/11 (9.1%)	0/11 (0.0%)	NA	NA

MedDRA = Medical Dictionary for Regulatory Activities, AE = adverse event
*Ulcer rate based on N=107 subjects who received the final device design. See Table 5 for additional gastric ulcer information.

The requirement for narcotic medications or injectable anti-emetic medications was not evaluated during the REDUCE Pivotal Trial.

Table 3 - Device-Related* Adverse Events by MedDRA Categorization, All *ReShape*-Treated Subjects, During Dual Balloon Exposure

	***ReShape* Treated Subjects N=264**	
Device-Related Adverse Events MedDRA Categorization	**# of events**	**Subjects % (n)**
Subject with any device-related adverse event	1042	99.2% (262)
Gastrointestinal disorders		
Vomiting	259	86.7% (229)
Nausea	183	61.0% (161)
Abdominal pain	178	54.5% (144)
Gastric ulcer	94	35.2% (93)
Dyspepsia	49	17.8% (47)
Eructation	46	16.7% (44)
Abdominal discomfort	38	13.3% (35)
Abdominal distension	30	11.0% (29)
Gastritis erosive	24	9.1% (24)
Gastroesophageal reflux disease	20	6.8% (18)
Constipation	14	5.3% (14)
Diarrhea	9	3.0% (8)

Device-Related Adverse Events MedDRA Categorization	*ReShape* Treated Subjects N=264	
	# of events	Subjects % (n)
Abdominal rigidity	8	2.3% (6)
Gastritis	4	1.5% (4)
Esophageal injury	4	1.1% (3)
Retching	3	1.1% (3)
Abdominal tenderness	2	0.8% (2)
Gastric hemorrhage	2	0.8% (2)
Epigastric discomfort	2	0.8% (2)
Gastric mucosa erythema	2	0.8% (2)
Abdominal pain upper	1	0.4% (1)
Abnormal feces	1	0.4% (1)
Change of bowel habit	1	0.4% (1)
Dysphagia	1	0.4% (1)
Feces hard	1	0.4% (1)
Flatulence	1	0.4% (1)
Obstruction gastric	1	0.4% (1)
Esophageal pain	1	0.4% (1)
Esophageal perforation	1	0.4% (1)
Esophagitis	1	0.4% (1)
Upper gastrointestinal hemorrhage	1	0.4% (1)
Gastrointestinal injury	1	0.4% (1)
Regurgitation	1	0.4% (1)
Metabolism and nutrition disorders		
Dehydration	4	1.5% (4)
Fluid intake reduced	4	1.5% (4)
Hypophagia	4	1.5% (4)
Decreased appetite	3	1.1% (3)
Hypokalemia	2	0.8% (2)
Respiratory, thoracic and mediastinal disorders		
Oropharyngeal pain	8	3.0% (8)
Hiccups	3	1.1% (3)
Hypoxia	1	0.4% (1)
Upper-airway cough syndrome	1	0.4% (1)
General disorders and administration site conditions		
Asthenia	5	1.9% (5)
Fatigue	1	0.4% (1)
Mucosal inflammation	1	0.4% (1)
Mucosal erosion	1	0.4% (1)
Non-cardiac chest pain	1	0.4% (1)
Nervous system disorders		
Dizziness	5	1.9% (5)
Headache	3	1.1% (3)
Dysgeusia	1	0.4% (1)
Other Conditions		
Back pain	3	1.1% (3)
Insomnia	2	0.8% (2)

Device-Related Adverse Events MedDRA Categorization	*ReShape* Treated Subjects N=264	
	# of events	Subjects % (n)
Psychological factor affecting medical condition	1	0.4% (1)
Anemia	1	0.4% (1)
Conjunctival hemorrhage	1	0.4% (1)
Pharyngeal injury	1	0.4% (1)
Blood potassium decreased	1	0.4% (1)

N, n = number, MedDRA = Medical Dictionary for Regulatory Activities
* This table presents device-related adverse events only. Procedure-related adverse events are presented in Table 8. An analysis of overlapping device- and procedure-related adverse events was not performed.

Table 4 - Severity Rating, Device-Related Adverse Events, All *ReShape*-Treated Subjects, During Dual Balloon Exposure

Device-Related Adverse Events Severity Rating*	Device-Related AEs % (n) N=1,042 total AEs
Asymptomatic	2.4% (25)
Mild	72.4% (754)
Moderate	23.8% (248)
Severe	1.4% (15)

N, n = number, AE = adverse event
*Asymptomatic = An adverse event that is not noticed by the subject and does not require additional therapy; Mild = An adverse event that is noticeable to the subject and may require additional therapy; Moderate = An adverse event that interferes with the subject's activities and requires intervention or additional therapies; Severe = An adverse event that is intolerable, or necessitates additional therapy or places the subject at immediate risk of harm.

Of the 264 ReShape-treated study subjects, 93 (35.2%) were adjudicated by the CEDMC to have gastric ulceration and 98% (91/93) were adjudicated as non-serious adverse events.

The *ReShape* Dual Balloon device underwent a minor modification to make the distal tip more atraumatic. This modified device was used to treat a total of 107 subjects, and the rate of ulcers was substantially reduced in these subjects. The incidence of gastric ulceration related to the two different device designs is shown in Table 5, which demonstrates a 74% reduction in the ulcer rate (p <0.0001).

Table 5 - Rates of Gastric Ulceration by *ReShape* Dual Balloon Device Design

Ulcer Rate	Original Tip Design *ReShape* Subjects Mean (n) (95% CI)	Modified Tip Design *ReShape* Subjects Mean (n) (95% CI)
N	225	107
% (n) 95% CI	39.6% (89) (33.2, 45.9%)	10.3% (11) (4.5, 16.0%)
Difference (95% CI) [1]	**-29.3% (-37.9, -20.7%)**	
p value [1]	**< 0.0001**	

n = number of subjects meeting condition, N = total number of subjects, CI = confidence interval
[1] p value and 95% CI calculated by chi square with continuity correction

Patients self-reported severity of nausea and vomiting at multiple time points during the study using the validated Rhodes Index instrument (Table 6).

Table 6 - Rhodes Index During Dual Balloon Treatment, All *ReShape*-Treated Subjects

Nausea and Vomiting During Dual Balloon Treatment Total Score 0 – 32	**Day 0 N = 264**	**Day 3 N = 252**	**Week 1 N = 258**	**Week 4 N =239**	**Week 12 N =239**	**Week 24 N = 233**
Median	0	10	3	0	0	0
Mean ± SD (Range)	0.3±1.8 (0, 16)	11.4±7.4 (0, 29)	3.9±4.5 (0, 23)	2.2±3.7 (0, 20)	0.9±2.2 (0, 15)	1.1±2.8 (0, 20)
Proportion with total score ≤ 8[1]	98.9%	41.3%	86.0%	93.3%	97.5%	97.4%

N = number, SD = standard deviation
Scale from 0 = none to 32 = severe
[1]A score of ≤ 8 approximates a mild symptom score

Patients self-reported severity of abdominal pain at multiple time points during the study using the validated Visual Analog Scale (Table 7).

Table 7 - Abdominal Pain Visual Analog Scale During Dual Balloon Treatment, All *ReShape*-Treated Subjects

Abdominal Pain During Dual Balloon Treatment Total Score 0 – 100	**Day 0 N = 264**	**Day 3 N = 252**	**Week 1 N = 258**	**Week 4 N =239**	**Week 12 N =239**	**Week 24 N = 233**
Median	0	30	10	0	0	0
Mean ± SD (Range)	0.4±2.2 (0, 20)	34.1±25.7 (0, 100)	14.9±19.0 (0, 90)	6.4±11.5 (0, 65)	3.9±10.5 (0, 80)	6.0±14.4 (0, 90)
Proportion with total score ≤ 25[1]	100.0%	44.3%	78.3%	92.5%	95.4%	90.6%

VAS = visual analog scale, N = number, SD = standard deviation
Scale 0 = none to 100 = severe
[1] A score of ≤ 25 approximates a mild symptom score

Table 8 - All Procedure-Related* Adverse Events by MedDRA Categorization, All Dual Balloon-Attempted Subjects, During Dual Balloon Exposure

	Dual Balloon-Attempted Subjects (N=265)	
Procedure-Related Adverse Events by MedDRA Categorization	**# of events**	**Subjects % (n)**
Total	183	42.3% (112)
Gastrointestinal disorders		
Vomiting	57	20.4% (54)
Nausea	26	9.8% (26)
Abdominal pain	12	4.5% (12)
Constipation	6	2.3% (6)
Esophageal injury	6	1.9% (5)
Abdominal distension	5	1.9% (5)
Gastroesophageal reflux disease	3	1.1% (3)
Eructation	3	1.1% (3)
Gastric hemorrhage	2	0.8% (2)
Gastrointestinal injury	2	0.8% (2)
Abdominal discomfort	1	0.4% (1)
Abdominal rigidity	1	0.4% (1)
Diarrhea	1	0.4% (1)
Dyspepsia	1	0.4% (1)
Esophageal perforation	1	0.4% (1)
Upper gastrointestinal hemorrhage	1	0.4% (1)
Respiratory, thoracic and mediastinal disorders		
Oropharyngeal pain	30	10.2% (27)
Hypoxia	6	2.3% (6)
Cough	1	0.4% (1)
Dyspnea	1	0.4% (1)
Hiccups	1	0.4% (1)
Productive cough	1	0.4% (1)
Upper airway obstruction	1	0.4% (1)
Nervous system disorders		
Headache	2	0.8% (2)
General disorders and administration site conditions		
Chest discomfort	1	0.4% (1)
Mucosal erosion	1	0.4% (1)
Mucosal hemorrhage	1	0.4% (1)
Injury, poisoning and procedural complications		
Procedural complication	2	0.8% (2)
Pharyngeal injury	1	0.4% (1)
Other conditions		
Myalgia	2	0.8% (2)

	Dual Balloon-Attempted Subjects (N=265)	
Procedure-Related Adverse Events by MedDRA Categorization	**# of events**	**Subjects % (n)**
Vertigo	1	0.4% (1)
Conjunctival hemorrhage	1	0.4% (1)
Pneumonia	1	0.4% (1)
Blood potassium decreased	1	0.4% (1)

N, n = number, MedDRA = Medical Dictionary for Regulatory Activities
* This table presents procedure-related adverse events only. Device-related adverse events are presented in Table 3. An analysis of overlapping device- and procedure-related adverse events was not performed.

Table 9 - Severity Rating, Procedure-Related Adverse Events, All Dual Balloon-Attempted Subjects, During Dual Balloon Exposure

Procedure-Related Adverse Events Severity Rating*	**Procedure-Related AEs % (n) N=183 total AEs**
Asymptomatic	4.9% (9)
Mild	85.8% (157)
Moderate	6.6% (12)
Severe	2.7% (5)

N, n = number, AE = adverse event
*Asymptomatic = An adverse event that is not noticed by the subject and does not require additional therapy; Mild = An adverse event that is noticeable to the subject and may require additional therapy; Moderate = An adverse event that interferes with the subject's activities and requires intervention or additional therapies; Severe = An adverse event that is intolerable, or necessitates additional therapy or places the subject at immediate risk of harm.

Early device deflation occurred in 6% (16/264) of successfully implanted *ReShape* Dual Balloon devices and involved a single balloon in all but one case. Eleven of these 16 deflations were heralded to the subject by the blue-green color of their urine resulting from the release of methylene blue dye from the balloon. Five of these events were found incidentally at scheduled retrieval. The subject with a dual deflation had not reported the first blue-green urine observation, but did report the second. No *ReShape* Dual Balloon device migrated out of the stomach at any time during this investigation, and no adverse events were associated with any device deflations.

DEMOGRAPHICS AND EFFECTIVENESS

The REDUCE Pivotal Trial baseline physical characteristics and demographics are shown below.

Table 10 - Baseline Physical Characteristics, Randomized Population

Parameter	***ReShape* (N=187) Mean (SD) N Median (Min, Max)**	**Control (N=139) Mean (SD) N Median (Min, Max)**	**Difference [95% CI]**
Age (years)	43.77 (9.51) 187 43.20 (22.7, 60.6)	44.04 (10.17) 139 42.50 (22.1, 60.2)	0.27 [-1.89, 2.43]
Body weight (lb)	209.24 (25.84) 187 205.30 (154.3, 302.8)	213.21 (25.46) 139 215.40 (162.5, 278.9)	3.97 [-1.69, 9.63]
BMI (kg/m^2)	35.32 (2.84) 187 35.30 (30.1, 40.1)	35.43 (2.63) 139 35.50 (30.2, 40.0)	0.10 [-0.50, 0.71]
Waist circumference (in)	43.44 (4.43) 187 43.27 (32.5, 54.0)	43.21 (4.36) 139 42.99 (34.0, 53.9)	-0.23 [-1.20, 0.73]
Hip circumference (in)	47.09 (3.51) 187 47.01 (36.0, 55.5)	47.74 (2.88) 139 47.48 (41.0, 54.0)	0.65 [-0.05, 1.35]

Table 11 - Baseline Sex, Ethnicity and Race, Randomized Population

Parameter	ReShape (N=187) % (n)	Control (N=139) % (n)
Sex (female)	95.2% (178)	95.0% (132)
Ethnicity (Hispanic/Latino)	8.0% (15)	5.8% (8)
Race:		
American Indian/Alaska Native	0.0% (0)	0.7% (1)
Asian	0.5% (1)	0.0% (0)
Black/African American	13.4% (25)	11.5% (16)
Native Hawaiian/Pacific Islander	0.0% (0)	0.0% (0)
White	81.8% (153)	85.6% (119)
Other/Refused	3.7% (7)	2.9% (4)

Co-primary and secondary endpoints were assessed based on %EWL (using the BMI = 25 method). Co-primary endpoints, both of which must be met for success:

1. Comparison of Treatment %EWL with Control %EWL at Week 24: an inferential test of whether the difference in the mean %EWL between the Treatment Group and Control Group at 24 weeks was significantly greater than a superiority margin 7.5%.

   H_0: $\%EWL_{RESHAPE} \leq \%EWL_{CONTROL} + 7.5\%$
   H_A: $\%EWL_{RESHAPE} > \%EWL_{CONTROL} + 7.5\%$

2. Treatment Group Responder Rate dichotomized at 25%EWL: an inferential test of whether the Treatment Group responder rate at 24 weeks was significantly greater than 35%.

   H_0: $RESPONDER_{25\%EWL - RESHAPE} - 35\% \leq 0\%$
   H_A: $RESPONDER_{25\%EWL - RESHAPE} - 35\% > 0\%$

Both primary effectiveness endpoints were met:

Table 12 – Primary Effectiveness Endpoints at 24 weeks

PEE #1 %EWL, Week 24	*ReShape* Mean	Control Mean	Difference (95% CI)`	P-value*
Intent to treat population	25.1%	11.3%	13.9% (9.1, 18.7%)	0.0041

*****Difference between groups, confidence limits and p-value from one-sided t-test all calculated by combining difference between groups across 10 imputed datasets and adjusted for gender and BMI by the method of Rubin (1987). P-value calculated accounting for a 7.5% lower limit.

PEE #2: Proportion of Responders %EWL ≥ 25	*ReShape* %	95% CI	P-value*
Intent to treat population	48.8%	(41.6, 56.0%)	< 0.0001

*****Normal one-sided t-test from combining estimates across 10 imputed datasets by the method of Rubin (1987) compared against the null of 35%.

The secondary endpoint evaluated weight loss maintenance six months following device removal in treated subjects with a measured and positive %EWL at 24 weeks using an inferential test. Specifically, the secondary endpoint assessed if significantly greater than 50% of subjects maintained 40% of their excess weight loss (the ratio of Week 48 %EWL/Week 24 %EWL was greater than 0.4). The control subjects were not evaluated for weight maintenance.

H_0: $RESPONDER_{0.40} - 50\% \leq 0\%$
H_A: $RESPONDER_{0.40} - 50\% > 0\%$

A total of 156 of 187 treatment subjects demonstrated a measured and positive %EWL at 24 weeks and were included in the secondary endpoint analysis. The secondary endpoint was not met.

Table 13 - Secondary Endpoint: Treatment Group Weight Maintenance Responders, Week 48

Secondary Endpoint: Proportion of Treatment Subjects with %EWL Week 48 / %EWL Week 24 ≥ 0.40	***ReShape* %**	**95% CI**	**P-value**
Intent-to-Treat Population	49.4%	(41.2, 57.5%)	0.5610*

* Normal one-sided t-test from combining estimates across 10 imputed datasets by the method of Rubin (1987) compared against the null of 50%

Table 14 - Distribution of Weight Loss Maintenance in Week 48 Completed Subjects*

Responder status	**Ratio of Week 48 %EWL to Week 24 %EWL**	**Total**	**%**
Non-responder	< 0 (gained more weight than lost)	26	20.6%
	0 - < 0.4 (regained more than 60% of lost)	31	24.6%
Responder	0.4 - < 1.00 (regained less than 60% of lost)	38	30.2%
	≥ 1.00 (continued to lose weight after balloon)	31	24.6%
	Total	126	100.0%

*****Completed subjects are defined as having a measured and positive %EWL at 24 weeks and a measured %EWL at 48 weeks. 126 of the 156 Intent-to-Treat subjects evaluated in the secondary endpoint had a measured %EWL at 48 weeks and were therefore completed subjects. 30 of 156 Intent-to-Treat subjects evaluated in the secondary endpoint were lost to follow-up between week 24 and week 48.

Table 15 – Weight Loss Parameters at 24 and 48 Weeks by Treatment Group

	***ReShape* Subjects**				**Control Subjects[1]**				
Analysis Group	**N**	**%EWL Mean (SD) (Min, Max)**	**%TBL Mean (SD) (Min, Max)**	**Pounds Mean (SD) (Min, Max)**	**N**	**%EWL Mean (SD) (Min, Max)**	**%TBL Mean (SD) (Min, Max)**	**Pounds Mean (SD) (Min, Max)**	**%EWL p-value[2]**
Intent-to-Treat at 24 weeks*	187	25.1%	6.8%	14.3	139	11.3%	3.3%	7.2	0.0041
Per Protocol at 24 weeks**	148	28.5%(20) (-16.9,130.7)	7.8%(5.4) (-6.3,24.7)	16.4(11.7) (-14.6,54.6)	120	13.4%(22.1) (-25.1,102.9)	3.9%(6.2) (-6.7,33.6)	8.5(14.1) (-14.1,86.8)	0.0017
Intent-to-Treat at 48 weeks***	156	18.2%	4.8%	9.9		NA	NA	NA	NA
Per Protocol at 48 weeks****	86	21.5%(29.1) (-36.9,121.0)	5.6%(7.5) (-7.2,28.9)	11.6(15.7) (-17.2,64.5)		NA	NA	NA	NA

[1] Control subjects weight loss parameters were not assessed at 48 weeks
[2] ITT group: One-sided t-test from combining difference between groups across 10 imputed datasets by the method of Rubin (1987) adjusted for gender and BMI. %EWL comparison accounts for a 7.5% lower limit. Per Protocol group: One-sided analysis of covariance adjusted for gender and BMI. %EWL comparison accounts for a 7.5% lower limit.
* Imputation technique does not allow computation of standard deviation or minima/maxima
** Completed 24 weeks of study follow-up and attended at least 75% of scheduled follow-up visits
*** Analysis includes 156 of 187 treatment subjects with a measured and positive %EWL at 24 weeks. Imputation technique does not allow computation of standard deviation or minima/maxima
**** Analysis includes 86 of 187 treatment subjects with a measured and positive %EWL at 24 weeks who completed 48 weeks of study follow-up and attended at least 75% of scheduled follow-up visits

The study was not powered for assessment of changes and did not include a pre-determined endpoint for factors associated with health improvements; however, data were collected to measure changes in comorbid conditions and quality of life. Results suggest that there were small, but not meaningful, improvements in comorbid parameters for diabetes, hypertension, and hyperlipidemia from baseline to 24 weeks in the treatment group, but these small improvements were not significantly different from the improvements seen in the control group. These changes from baseline generally persisted through 48 weeks for the treated subjects (the control subjects were not evaluated after 24 weeks for comparison). Statistically significant differences were seen in waist (0.94 inches) and hip circumference (0.62 inches) of treated subjects compared to control subjects at 24 weeks.

Results also showed a statistically significant improvement in quality of life measures (IWQoL-Lite Total and SF-36: physical functioning) at 24 weeks in the treated subjects as compared to the control subjects; these improvements generally persisted in the treated subjects to 48 weeks. No differences were seen in other categories of the SF-36 survey or the Three Factor Eating Questionnaire (TFEQ).

HOW SUPPLIED

The *ReShape* Integrated Dual Balloon System (Catalog No. RSM101) is supplied sterile and contains (1) Intragastric Dual Balloon/Delivery Catheter Assembly, (1) guidewire, and (1) patient identification card. The *ReShape* Valve Sealant (Catalog No. RSM900) and the *ReShape*™ Removal Catheter (Catalog No. RSM210) are packaged separately.

Inspect the packaging and contents prior to use. Do not use if sterile packaging integrity is compromised and/or the device appears to be damaged as this may cause injury to the patient.

Adjunct devices and materials for use in the *ReShape* Dual Balloon insertion procedure (not included):

1. Gastroscope
2. (2) 500 cc sterile saline bags
3. Methylene blue (USP 10mg/mL concentration)
4. *ReShape* Infiltration Pump (KIP-II-RS, manufactured by HK Surgical)
5. (2) Sterile Single Spike Tubing (ITS-10-RS, manufactured by HK Surgical, or equivalent)

Adjunct devices and materials for use in the *ReShape* Dual Balloon removal procedure (not included):

1. Gastroscope
2. Suction Pump and Accessories
3. Large endoscopic (rat tooth) graspers
4. Large endoscopic snare

DIRECTIONS FOR USE

***ReShape* Dual Balloon System Preparation:**

1. Prepare saline solution

1.1. Obtain two 500cc bags of sterile saline.

1.2. Inject and mix 2cc of methylene blue (USP 10mg/mL concentration) into each 500cc bag.

1.2.1. NOTE: If using a different methylene blue concentration, adjust the volume accordingly

1.2.2. NOTE: Methylene blue provides a visual indicator (i.e., blue-green urine) when the saline solution is released from a deflated balloon.

2. Prepare balloon fill volumes

2.1. Set up the automated pump. Refer to the *ReShape* Infiltration Pump's Instructions for Use for setup and operating information for the *ReShape* Infiltration Pump and its accessories.

2.2. Attach inflation pump tubing to each saline bag.

2.3. Alternate manual inflation method: The manual inflation method requires (1) 20mL Luer-lock syringe, (1) 122cm IV tubing with spike, (1) 3-way valve, and (1) pressure tubing set. Assemble the inflation instruments.

Verify that the instruments are connected such that the solution is pumped from the saline bag to the distal end of the pressure tubing intended for connection to the balloon catheter.

2.4. Determine the desired inflation volume for each balloon. A fill volume of 375 cc is recommended for patients < 64.5" in stature and 450 cc for patients ≥ 64.5" in stature.

2.5. Use the pump to purge the inflation tubing of air and to remove any air from the 500cc saline bag.

2.5.1. **NOTE**: Use gloves and employ proper handling techniques to minimize the potential of introducing microbes into the balloon. Some microbes may have the potential to produce gas inside the balloon.

2.6. Use the pump to remove excess saline solution from the bag to achieve the desired fill volume. For example, if the desired fill volume is 450cc, remove 50cc of solution from the saline bag.

2.7. Repeat the steps above for the second saline bag.

3. Prepare the valve sealant

3.1. One package (containing 2 syringes) of *ReShape* Valve Sealant (Catalog No. RSM900) is required for the *ReShape* Dual Balloon insertion procedure.

3.2. Refer to the Valve Sealant's Instructions for Use for setup information.

3.3. In the event that the *ReShape* Valve Sealant is not available, fill two Luer-lock syringes each with 6cc of USP-grade mineral oil.

Device Placement:

1. Confirm patient compliance with the recommended pre-procedure diet:

1.1. 48 hours prior to the procedure: Soft food only, no meat in any form

1.2. 24 hours prior to the procedure: Clear liquids only

1.3. 12 hours prior to the procedure: No food or liquids by mouth

2. Administer an oral anesthetic spray if desired and place an adult-size endoscopic bite block into the patient's mouth.

3. Position the patient in a left lateral decubitus position.

4. Administer monitored anesthesia care (MAC) sedation.

5. Perform an esophagogastroduodenoscopy to verify the patient does not have any conditions that would preclude balloon placement.

5.1. **CAUTION:** If food or liquid is present in the stomach at the time of the placement procedure, it is recommended that the procedure be delayed until a later time.

6. Deliver the guidewire through the working channel of the scope. Place the distal portion of the guidewire into the duodenum and position the guidewire along the greater curvature of the stomach.

7. Note the depth markings on the endoscope that correspond to the endoscope tip placed just below the gastroesophageal junction (GEJ).

8. Remove the endoscope while maintaining the guidewire in the stomach.

9. Remove the *ReShape* Dual Balloon from the package, remove the balloon cover and apply a small amount of esophageal lubricant to the balloon segment to facilitate insertion.

10. Insert the catheter over the guidewire, through the mouth and esophagus and into the stomach. Use the depth markings on the delivery catheter to help position the balloon segment distal to the GEJ.

11. Reinsert the endoscope into the stomach alongside the balloon delivery catheter and verify correct positioning (see below). Reposition the balloon as necessary.

11.1. The balloon-catheter detent is just distal to the gastroesophageal junction.

11.2. The balloon segment is lying along the greater curvature of the stomach.

11.3. The distal balloon does not extend past the pylorus.

12. Connect the inflation tubing to the proximal balloon fill tube (catheter lanyard 1) and inflate to the desired volume. Monitor inflation under endoscopic visualization.

12.1. **NOTE:** If it is determined that the patient anatomy will not accommodate at least 375cc in the proximal balloon, discontinue the placement procedure, aspirate inflation fluid, and remove the *ReShape* Dual Balloon device.

13. Once inflation is complete, attach the first Valve Sealant syringe to the proximal balloon fill tube (catheter lanyard 1) and inject 6cc of sealant into the proximal balloon.

13.1. **WARNING:** The *ReShape* Valve Sealant is necessary to seal the device valves and prevent balloon leakage. Failure to use the specified amount of Valve Sealant will result in balloon leakage and deflation, and increase the risk of intestinal obstruction (and therefore possible complications related to intestinal obstruction).

14. Connect the inflation tubing to the distal balloon fill tube (catheter lanyard 2) and inflate to the desired volume. Monitor inflation under endoscopic visualization.

14.1. **NOTE:** If it is determined that the patient anatomy will not accommodate at least 375cc in the distal balloon, discontinue the placement procedure, aspirate inflation fluid from proximal and distal balloon, and remove the *ReShape* Dual Balloon device.

15. Once inflation is complete, attach the second Valve Sealant syringe to the distal balloon fill tube (catheter lanyard 2) and inject 6cc of sealant into the proximal balloon.

15.1. **WARNING:** The *ReShape* Valve Sealant is necessary to seal the device valves and prevent balloon leakage. Failure to use the specified amount of Valve Sealant will result in balloon leakage and deflation, and increase the risk of intestinal obstruction (and therefore possible complications related to intestinal obstruction).

16. Once the Valve Sealant has been added to each fill tube, the delivery catheter can be disengaged from the filled balloon.

16.1. **NOTE:** Do NOT disconnect the delivery catheter until Valve Sealant has been added to each balloon.

17. Position the endoscope proximal to the delivery catheter detent. Grasp the catheter and endoscope together and withdraw both in tandem against the gastroesophageal junction until the balloon is released into the stomach. Continue to withdraw both the catheter and endoscope together and remove from the mouth.

17.1. **CAUTION:** Keep the endoscope tip at least 2-3 cm proximal to the delivery catheter detent while disengaging the balloon and removing the catheter. The combined diameter of the catheter detent and the endoscope side-by-side may cause esophageal injury.

18. Reinsert the endoscope to inspect the oropharynx and esophagus.

19. Dispose of device in accordance with institution's standard protocol for disposal of biohazard materials.

20. Ensure that the patient receives the patient identification (ID) card.

20.1. Place the lot identification sticker on the ID card and complete the other sections of the patient ID card.

Device Removal:

1. Confirm patient compliance with the recommended pre-procedure diet:

1.1. 48 hours prior to the procedure: Soft food only, no meat in any form

1.2. 24 hours prior to the procedure: Clear liquids only

1.3. 12 hours prior to the procedure: No food or liquids by mouth

2. The *ReShape* Removal Catheter (Catalog # RSM210) must be used to drain the saline from each balloon.

2.1. NOTE: Refer to the instructions for use (IFU) for the *ReShape* Removal Catheter.

3. Administer an oral anesthetic spray if desired and place an adult-size endoscopic bite block into the patient's mouth.

4. Position the patient in a left lateral decubitus position.

5. Administer monitored anesthesia care (MAC) sedation.

5.1. CAUTION: In the event of an emergency removal by a physician untrained in the procedure, endotracheal intubation of the patient is recommended to reduce the risk of aspiration.

6. Perform an esophagogastroduodenoscopy to inspect the balloons and the stomach.

6.1. CAUTION: If food or liquid is present in the stomach at the time of the procedure, it is recommended that the procedure be delayed until a later time. If this is not possible, endotracheal intubation of the patient is recommended to reduce the risk of aspiration.

7. With the endoscope tip positioned at the proximal balloon, insert the Removal Catheter into the endoscope channel.

8. Connect a suction source to the Removal Catheter. Keep the valve on the stopcock closed.

9. Advance the Removal Catheter through the endoscope until the catheter tip lightly touches the balloon surface.

9.1. NOTE: Applying excess force with the catheter tip against the balloon surface increases the risk that the balloon will tear during needle advancement.

10. While maintaining a perpendicular orientation and light pressure on the catheter tip at the balloon surface, turn the catheter handle clockwise to rotate and advance the needle to rotationally cut the balloon. Continue to turn the handle until it reaches a stop.

10.1. NOTE: If the balloon tears during needle advancement, withdraw the Removal Catheter from the endoscope and use the endoscope to suction the saline that was released from the balloon

11. Advance the catheter through the cut hole until the balloon surface reaches the second line marker on the catheter shaft.

12. Turn the catheter handle counter-clockwise to retract the needle. Continue to turn the handle until it reaches a stop.

13. After retracting the needle, advance the catheter through the cut hole until the balloon surface reaches the triple line marker on the tubing.

14. Open the valve on the catheter and aspirate the saline from the balloon. Continue aspiration until the proximal balloon is completely deflated.

14.1. NOTE: Do not move the endoscope or catheter while the catheter is inside of the balloon. Doing so may pull the catheter out of the balloon or otherwise cause fluid to leak out of the balloon.

15. When aspiration is complete, disconnect the suction source from the catheter to relieve the vacuum inside of the balloon.

16. Remove the catheter from the flattened balloon.

17. Repeat above steps to deflate the distal balloon with the same Removal Catheter.

18. Remove the Removal Catheter from the endoscope channel.
18.1. NOTE: If any saline had leaked from the balloon during the drainage procedure, use the endoscope to suction that fluid from the stomach before proceeding.

19. Insert an endoscopic grasper (e.g. Olympus large rat tooth grasping forceps) through the endoscope channel and make 1-2 large holes in each balloon's wall. This will allow venting of any residual air or fluid in the balloons.

19.1. NOTE: Failure to ventilate residual air or fluid may increase the force required to remove the balloon.

20. Insert an endoscopic snare (e.g., Cook Medical large hexagonal snare) through the endoscope channel and position it completely around the proximal balloon end cap.

21. With the snare securely positioned around the cap, retract the snare with a firm grasp to the tip of the endoscope.

22. Maintain a firm grasp with the snare and withdraw the endoscope and snare in tandem from the patient until the balloon is retrieved from the mouth.

22.1. CAUTION: A laryngoscope and Magill forceps should be available in the event the balloon slips off of the snare and must be retrieved with forceps.

23. Reinsert the endoscope to inspect the oropharynx, esophagus, and stomach.

24. Dispose of device in accordance with institution's standard protocol for disposal of biohazard materials.

PATIENT IDENTIFICATION CARD

Enclosed with each *ReShape* Dual Balloon is a Patient identification (ID) Card. To complete the Patient ID Card, place one device identification sticker on the card. Stickers are located on the internal product packaging attached to the label. If a sticker is unavailable, the lot number may be copied by hand from the device label. Patients should be provided with these cards for reference.

Magnetic Resonance (MR) Compatibility

The *ReShape* Dual Balloon is MR safe.

The *ReShape* Delivery Catheter and Removal Catheter are MR unsafe and are known to pose hazards in all MR imaging environments.

STORAGE AND HANDLING

Handle with care. Packages should be stored in a manner that protects the integrity of the package and dust barrier.

PATENT: http://www.pro.reshapeready.com/patents

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San Clemente, CA 92672 USA
Telephone: 844-YES-RESHAPE

Symbol	
	Lot number
	Model number
	Use by
	Consult instructions for use
	Attention: See Instructions for Use
	Do not use if package is damaged
	Single use only. Do not reuse.
	Manufacturer
	Sterilized using irradiation
	Do not resterilize