

**UNITED STATES DISTRICT COURT  
DISTRICT OF DELAWARE**

**FULLILLIUM, INC.,**

**Plaintiff,**

**vs.**

**SV HEALTH INVESTORS, LLC**

**Defendant.**

Case No. \_\_\_\_\_

**DEMAND FOR JURY TRIAL**

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Fulfillium, Inc. (“Fulfillium” or “Plaintiff”), for its Complaint against SV Health Investors, LLC (“Defendant” or “SV Health”) alleges the following:

**NATURE OF THE ACTION**

1. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

**THE PARTIES**

2. Fulfillium is a corporation organized and existing under the laws of the State of Delaware, with an address at 1136 Orchard Avenue, Napa, California 94558.

3. On information and belief, SV Health is a limited liability company organized and existing under the laws of the State of Delaware with its principal place of business at One Boston Place, 201 Washington Street, Suite 3900, Boston, Massachusetts 02108. SV Health can be served via its registered agent The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware, 19801. SV Health maintains a business in the State of California at 1700 Owens Street, Suite 585, San Francisco, CA 94158.

4. On information and belief, SV Health was formerly known as SV Life Sciences LLC (“SV Life Sciences”) and was formed when SV Life Sciences, LLC reorganized as SV Health.

5. On information and belief, SV Life Sciences LLC funded, owned and controlled ReShape Medical, Inc.

6. On information and belief, ReShape Medical, Inc. was acquired by EnteroMedics, Inc. at which point ReShape Medical LLC was created.

7. On information and belief, EnteroMedics, Inc. changed its name to ReShape Lifesciences, Inc.

8. On information and belief, SV Health and/or its predecessor SV Life Sciences have directed, controlled, actively induced and/or conspired with George Wallace, Intersect Partners LLC, ReShape Medical, Inc. and/or ReShape Medical LLC, to take the actions that form the basis for this Second Amended Complaint.

9. The website of SV Health Investors states that “SV Health Investors, formerly SV Life Sciences, is a leading healthcare and life sciences venture capital and growth equity firm.” SV Health Investors and its predecessor SV Life Sciences have at all relevant times held one or more seats on ReShape Medical, Inc.’s Board of Directors.

10. The first heading of the About Us page of SV Health Investors’ website is “Hands-on business partners.” Exhibit 5. The page explains that SV Health Investors “work hands-on with our portfolio companies as trusted advisers and partners from formation to exit. We help them develop business strategy, make connections within our networks, and guide them through both smooth and turbulent times toward a successful exit.” *Id.* According to the website, “[t]he SV team has more than 400 aggregate years of healthcare operating experience – which means we can work as true partners with our entrepreneurs, and develop strong relationships with them through the full life cycle of their ventures.” *Id.* George Wallace performed this role as a venture partner at SV Health prior to the founding of ReShape Medical, Inc.’s predecessor and concurrently served as the chief executive officer and board director of ReShape Medical, Inc. since its founding.

11. On information and belief, a member SV Health and/or a related or predecessor entity has occupied at least one seat on the Board of ReShape Medical, LLC and/or ReShape Medical, Inc. and/or ReShape Lifesciences.

### **JURISDICTION AND VENUE**

12. Upon information and belief, SV Health and/or SV Life Sciences has induced ReShape Medical LLC and/or ReShape Medical, Inc. and/or ReShape Lifesciences to sell and offer to sell products and services throughout the United States, including in this judicial district with knowledge that those products and services incorporate infringing technology knowing that they would be sold in this judicial district and elsewhere in the United States.

13. This is an action for patent infringement arising under the Patent Laws of the United States, Title 35 of the United States Code, respectively.

14. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

15. Venue is proper in this judicial district under 28 U.S.C. § 1400(b) because SV Health is incorporated under the laws of the state of Delaware and, therefore, resides in this district.

16. On information and belief, SV Health is subject to this Court's general and specific personal jurisdiction because SV Health has sufficient minimum contacts within the State of Delaware and this District, pursuant to due process and/or the Delaware Long Arm Statute, because SV Health purposefully availed itself of the privileges of conducting business in the State of Delaware and in this District, because SV Health regularly conducts and solicits business within the State of Delaware and within this District, and because Fulfillium's causes of action arise directly from SV Health's business contacts and other activities in the State of Delaware and this District.

### **GENERAL ALLEGATIONS**

17. Dr. Richard D. Y. Chen was born in Taiwan in 1958 and emigrated to the United States in 1972. Dr. Chen obtained an undergraduate degree in biochemistry and molecular biology from Harvard University in 1979. Dr. Chen next attended medical school at Northwestern University and obtained an M.D. in 1983. Dr. Chen performed his internship in

general surgery and continued in his residency in neurosurgery at the Johns Hopkins Hospital in the 1980s.

18. Dr. Chen obtained a Master's Degree in Business Administration from Stanford University in 1990. Following matriculation, Dr. Chen began working in the investment banking department at Morgan Stanley & Company. Thereafter, Dr. Chen continued working in financial services making investments in and assisting start-up companies primarily in the technology sector.

19. In 1999, Dr. Chen started conceiving innovative ideas of his own by combining his experiences at the crossroads of medicine and technology. After the tragic events of September 11, 2001, prospects in the technology investment markets began to slow. Dr. Chen decided to focus on developing and commercializing these ideas into entrepreneurial ventures.

20. Dr. Chen conceived of a bariatric medical device and procedure whereby a novel balloon device is delivered endoscopically to reduce the interior volume of the stomach and impede the flow of ingested food and thereby effectively reduce the calories consumed. To mitigate potentially fatal consequences of premature rupture and migration, which were significant deficiencies in earlier devices within this class, safety was provided by two or more chambers filled with fluids.

21. Because obesity is a complex, multifactorial disease, Dr. Chen invested at least two years' time i) analyzing critically over a thousand scientific papers relating from the genetic basis of obesity to interventions in clinical therapy to the psychosocial impact of the disease, and ii) attending scientific research conferences on the basic underpinnings of the field and major medical conferences in the United States and overseas to learn about the state of the art in therapy and how the various medical specialties played their role in its treatment. Gaining insight from these activities, Dr. Chen further refined key elements of his idea and its implementation into everyday medical practice.

22. Dr. Chen then presented his idea, on a confidential basis, to leading researchers and clinicians in the field, including the former presidents of the American Gastroenterology Association, the American Society of Bariatric Surgeons and its overseas counterpart, the

International Federation for the Surgery of Obesity. Practically everyone he contacted responded favorably with the willingness to commit to participate further in developing the medical device and procedure. Each of these disclosures was subject to a mutual understanding and obligation of confidentiality. Only individuals who were under written obligations of confidentiality were provided information regarding Fulfillium's trade secrets.

23. Dr. Chen contributed funds and his intellectual property to form Fulfillium, Inc. in 2004 and filed his first provisional patent application on May 3, 2004. Dr. Chen raised seed capital from friends and family to take the idea to the next stage of development. Dr. Chen attended trade shows in medical device manufacture. Dr. Chen engaged consultants including engineers to help develop the device and former regulators to explore the pathway for FDA approval. Prototypes were constructed and animal lab facilities were evaluated.

24. Dr. Chen next embarked on raising venture capital to prove the concept. Given his past experience in the venture business, Dr. Chen adopted a set of practices for disclosure to protect the intellectual properties he developed. Under this set of practices, Dr. Chen did not disclose any trade secret information to anyone unless he had confirmed an agreement that it would be kept confidential. On January 25, 2005, Dr. Chen spoke with Dr. Samuel Wu, M.D. of SV Life Sciences (predecessor of SV Health) to discuss Fulfillium's technology on a confidential basis. All parties confirmed that the conversations regarding Dr. Chen's ideas were subject to an oral agreement of confidentiality. On February 10, 2005, Dr. Chen attended a meeting including the SV Life Sciences team in Boston led by partner David Milne via a videoconference call hosted at the SV Life Sciences offices at 950 Tower Lane, Ste. 1535, Foster City, California. Dr. Chen understood the meeting to be confidential and, consistent with that, Dr. Chen's presentation slides were all marked "STRICTLY CONFIDENTIAL." All parties confirmed that the conversations surrounding this meeting were subject to an oral agreement of confidentiality.

25. In addition, SV Life Sciences representatives had due diligence calls with various Fulfillium scientific advisors. These due diligence phone calls were for expert validation of Fulfillium's therapeutic concept and did not include presentations of Fulfillium's product development plans or trade secrets.

26. Dr. Wu informed Dr. Chen that the due diligence was “looking good” and that SV Life Sciences was contemplating a term sheet. Dr. Wu noted that although he, in California, had taken a point person role in the development of the deal, SV Life Sciences’ medical device group was headquartered in Boston and he was not part of the group. Thus, going forward SV Life Sciences would prefer to partner with a venture capital firm in California who could more effectively monitor Fulfillium’s activities.

27. Among other venture capital firms, Dr. Chen separately gave a confidential presentation to Sprout Partners. Dr. Chen delivered the presentation to Sprout partners Jeani Delagardelle at Sprout’s Menlo Park office and Andrew Firlik, M.D. via conference call on March 4, 2005. Sprout and Fulfillium understood that the conversations surrounding this presentation were confidential because the parties previously signed and executed a written non-disclosure agreement. Ms. Delagardelle later invited Dr. Chen to attend as Sprout’s guest at the annual American Heart Association luncheon, a key event in the industry. Ms. Delagardelle took on a lead role by referring another venture capital firm as a potential co-investor. Dr. Chen eventually made an introduction between SV Life Sciences and Sprout.

28. During the foregoing meetings and communications with SV Life Sciences and Sprout, Dr. Chen provided confidential and detailed disclosures of Fulfillium’s preferred clinical trial design and regulatory approval strategy. All of the relevant parties to the foregoing meetings and communications understood the conversations that occurred were subject to either oral or written agreements of confidentiality.

29. On information and belief, neither SV Life Sciences nor Sprout had any substantial previous knowledge or experience with balloon treatments for obesity.

30. On information and belief, all of SV Life Sciences’ and Sprout’s knowledge concerning Dr. Chen’s novel balloon designs for obesity as of the Spring of 2005 was supplied by Dr. Chen.

31. In the Spring of 2005, Ms. Delagardelle indicated that the due diligence process would be delayed somewhat due to the fact that the healthcare group principals of Sprout were forming a new firm, New Leaf Venture Partners. Ms. Delagardelle asked Dr. Chen if this would

pose a problem. Dr. Chen responded that time was of the essence but a short delay under the circumstances would be manageable.

32. Meanwhile, Dr. Chen continued to interface with SV Life Sciences. SV Life Sciences arranged for Dr. Chen to meet George Wallace (venture partner for SV Life Sciences) on May 16, 2005 at a restaurant in Chicago. During the meeting Mr. Wallace proposed terms and conditions under which he would work with Fulfillium. In addition to other compensation, Mr. Wallace demanded greater than 25% stake in Fulfillium after the first round of financing by venture capital firms. Given the ownership dilution that typically occurs during the first round of financing, Mr. Wallace was effectively demanding majority ownership of Fulfillium. Dr. Chen noted that Mr. Wallace's requested equity share was more than two to four times greater than that typically allotted to a CEO brought in to run a company at Fulfillium's stage of development. Mr. Wallace offered no justification other than to say that he needed to compensate his business partner, a practicing radiologist in Minnesota, and would not proceed without including his business partner. Dr. Chen never disclosed the trade secrets to Mr. Wallace.

33. Thereafter, no further discussion took place between Mr. Wallace and Dr. Chen. Instead, unbeknownst to Dr. Chen, decision makers in SV Life Sciences sought to launch a new company with Mr. Wallace as the CEO based on Fulfillium's technology and trade secrets, which were misappropriated despite the repeated oral agreements of confidentiality with SV Life Sciences. In the early summer of 2005, Ms. Delagardelle of New Leaf sent a brief email to Dr. Chen advising that New Leaf was considering a deal that SV Life Sciences was proposing. Dr. Chen presumed that SV Life Sciences was proposing bringing to market an alternative solution that would be different from the technology developed and confidentially disclosed by Dr. Chen. Dr. Chen would later discover that SV Life Sciences' venture headed by Mr. Wallace was premised not on some alternative solution but rather Fulfillium's technology and trade secrets.

34. On information and belief, Mr. Wallace's new company, called Abdominis, Inc., was formed during the summer of 2005 and was funded by New Leaf and SV Life Sciences. Upon information and belief, both SV Life Sciences and New Leaf not only provided capital, but

as typical early stage venture capital firms, provided direct guidance in the company's development and controlled the operations of the company through their board membership.

35. Abdominis was subsequently renamed ReShape Medical, Inc. Hereafter, "Reshape Medical, Inc." will refer to Abdominis, Inc. and its successor-in-interest Reshape Medical, Inc.

36. As is typical for a medical start-up company, ReShape Medical, Inc. operated in "stealth mode" during development. ReShape Medical, Inc. started pivotal clinical trials in 2012 and applied for FDA approval in 2014. The FDA granted Pre-Marketing Approval to the ReShape Duo™ device and treatment method on July 28, 2015.

37. When ReShape Medical, Inc. emerged from stealth mode and began commercial operations, Dr. Chen learned that ReShape Medical, Inc. had copied his trade secrets, including his entire clinical trial "playbook." ReShape Medical, Inc. copied, among other things, Dr. Chen's clinical trial design and his selection of the principal investigator.

38. On information and belief, the board of directors and officers of ReShape Medical, Inc. knew or had reason to know of the foregoing facts and events at the time ReShape Medical, Inc. first submitted the ReShape Duo™ product for FDA approval in 2012.

39. On October 2, 2017, EnteroMedics, Inc. acquired ReShape Medical, Inc. for cash and securities in the value of approximately \$38 million. This acquisition and merger was announced on October 3, 2017.

<http://ir.enteromedics.com/releasedetail.cfm?ReleaseID=1042545>. ReShape Medical LLC is an additional entity that resulted from this merger. On October 23, 2017, EnteroMedics, Inc. announced its name change to ReShape Lifesciences Inc.

<http://ir.enteromedics.com/releasedetail.cfm?ReleaseID=1044913>.

#### **COUNT I – INFRINGEMENT OF U.S. PATENT NO. 9,456,915**

40. Fulfillium repeats the allegations of paragraphs 1-39 above as though fully set forth herein.

41. On October 4, 2016, U.S. Patent No. 9,456,915 ("the '915 patent"), entitled "Methods, Devices, and Systems for Obesity Treatment," was duly and legally issued by the



United States Patent and Trademark Office. A true and correct copy of the '915 patent is attached as Exhibit 1.

42. Fulfillium is the assignee and owner of the right, title and interest in and to the '915 patent, including the right to assert all causes of action arising under said patents and the right to any remedies for infringement of them by at least an assignment dated July 17 2018. Ex. A.

43. On information and belief, ReShape Medical LLC and ReShape Lifesciences are engaged in the business of making, using, selling, offering to sell, and/or importing medical devices. A description of ReShape Medical LLC and ReShape Lifesciences' business is available on its business website, which is located at <http://pro.reshapeready.com>; <https://reshapeready.com/>. A screenshot of the homepage of ReShape Medical LLC's business website is attached as Exhibit 3.

44. As part of its business, each of ReShape Medical LLC and ReShape Lifesciences (hereinafter "Infringing ReShape Entities") makes, uses, offers to sell, sells, and/or imports a dual intragastric balloon for weight loss, including ReShape's "Duo Balloon" device, which is placed inside the patient's stomach for weight loss. The Infringing ReShape Entities have purposefully sold and offered for sale such Duo Balloon devices throughout the United States.

45. Upon information and belief, the Infringing ReShape Entities have and continue to directly infringe at least claims 1-2 and 4-27 of the '915 patent by making, using, selling, importing and/or providing and causing to be used medical devices for weight loss, including but not limited to, those sold under the name ReShape Duo Balloon (the "Infringing Instrumentalities" or "ReShape Balloon"). For clarity, the terms "Infringing Instrumentalities" and "ReShape Balloon" are understood to include the balloon device intended for delivery into the gastric cavity, as well as any delivery system for that balloon device.

46. Upon information and belief, SV Health has and continues to indirectly infringe at least claims 1-2 and 4-27 of the '915 patent by, among other things, and with specific intent or willful blindness, actively aiding and abetting the Infringing ReShape Entities to directly infringe

at least claims 1-2, and 4-27 of the '915 patent by the Infringing ReShape Entities sale of the Infringing Instrumentalities.

47. Upon information and belief, SV Health controls or has controlled a substantial portion of the day to day business activities of the Infringing ReShape Entities.

48. Representative claim 1 of the '915 patent recites a "gastric balloon structure for deploying in a gastric cavity of a patient, comprising: at least two isolated non-concentric inflatable chambers, wherein each chamber of the at least two isolated non-concentric inflatable chambers has a respective inflated state volume such that deflation of any single chamber of the at least two isolated non-concentric inflatable chambers leaves the inflated state volume of the remaining chambers of the at least two isolated non-concentric inflatable chambers unaffected." The Infringing Instrumentalities infringe claim 1 of the '915 patent. The ReShape Dual Balloon "is a temporary implant designed to facilitate weight loss by occupying space in the stomach." ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, p. 1, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). The figure below, taken from ReShape's instruction manual, shows the dual balloon in a patient's stomach. The ReShape website states that "[i]n the unlikely event of individual gastric balloon leakage or deflation, the independently sealed *ReShape* weight loss balloons are designed to minimize risk of migration or obstruction." <http://pro.reshapeready.com/about-reshape/#theadvantages>. In other words, each balloon inflates and deflates independently. See also <https://www.youtube.com/watch?v=U91FsjtMf3o>.

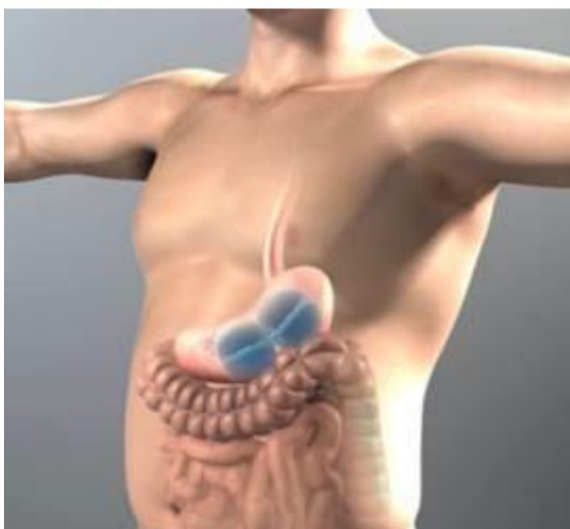


Figure 1. *ReShape* Dual Balloon in the Stomach

49. Claim 1 of the ‘915 patent further recites “a valve system for introducing a fluid into the at least two isolated non-concentric inflatable chambers and for retaining, upon inflation, the fluid in the at least two isolated non-concentric inflatable chambers.” The chambers of the ReShape balloons are filled after they are positioned in the patient’s stomach. ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, pp. 16-17, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). “The ReShape™ Valve Sealant is necessary to seal the device valves and prevent balloon leakage.” *Id.*; see also <https://www.youtube.com/watch?v=U91FsjtMf3o>; U.S. Pat. No. 8,142,469 at Fig. 1, 3-5.

50. Claim 1 of the ‘915 patent further recites “a flexible central spine spanning a gap between and fixedly attached to both a first chamber of the at least two isolated non-concentric inflatable chambers and a second chamber of the at least two isolated non-concentric inflatable chambers; wherein the gastric balloon structure, in its inflated state, assumes a curved shape conforming to a natural three-dimensional kidney shape of the gastric cavity, such that the flexible central spine flexibly conforms, upon at least partially filling the at least two isolated non-concentric inflatable chambers, the gastric balloon structure to the natural three-dimensional kidney shape of the gastric cavity.” The flexible central spine element is illustrated in the video

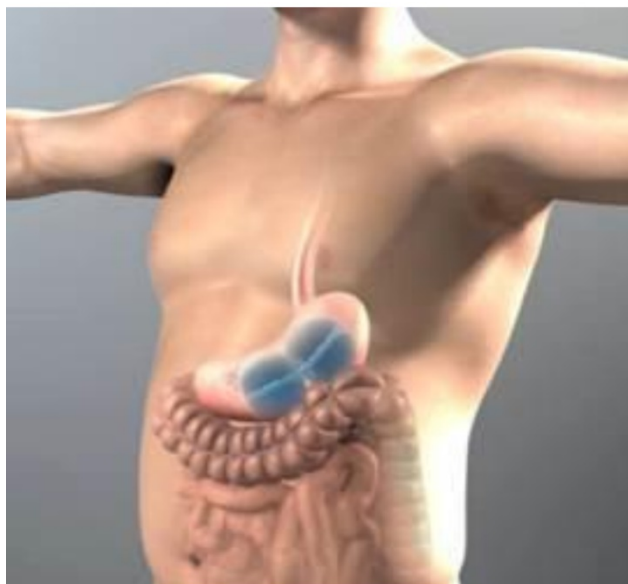
provided on ReShape's website, a frame from which is reproduced below. See

<https://reshapeready.com/reshape-cc/>; see also

<https://www.youtube.com/watch?v=U91FsjtMf3o>.



The conformance of the dual balloon to the stomach of the patient is shown in the image above and is also illustrated in Figure 1 of ReShape's instructions for use, reproduced below.



**Figure 1. ReShape Dual Balloon in the Stomach**

51. The final recitation in claim 1 of the '915 patent is that "a respective fluid volume for filling each chamber of the at least two isolated non-concentric inflatable chambers is selected based upon dimensions of the gastric cavity of the patient." ReShape's instructions for use state as follows:

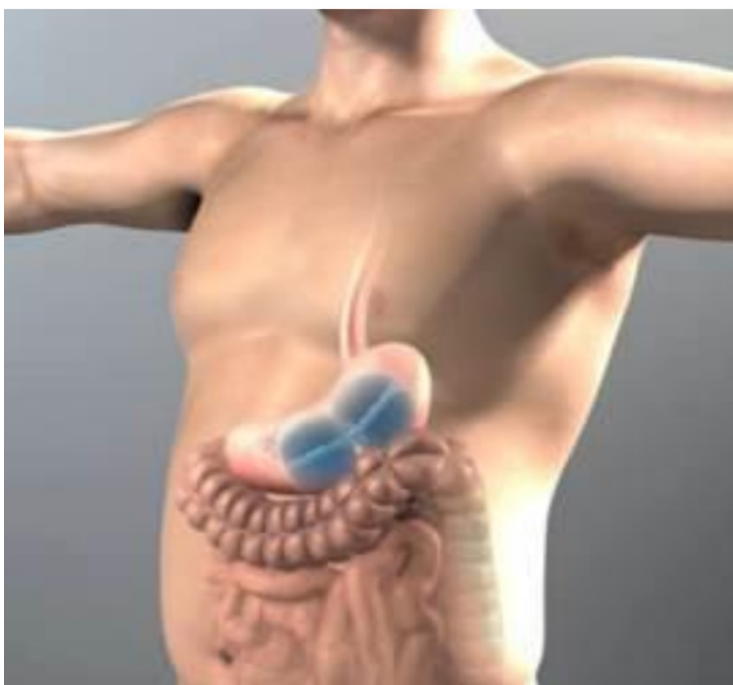
2.4. Determine the desired inflation volume for each balloon. A fill volume of 375 cc is recommended for patients < 64.5" in stature and 450 cc for patients  $\geq$  64.5" in stature.

See [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf) at

16. ReShape instructs the user to determine the size of the patient and to select a corresponding fill volume for the balloon structure.

52. Claim 2 of the '915 patent generally recites the gastric balloon structure of claim 1, wherein the gastric balloon structure is designed to provide for modulated passage of food through the gastric cavity upon inflation.

53. The Infringing Instrumentalities infringe claim 2 of the '915 patent. The ReShape Dual Balloon "is a temporary implant designed to facilitate weight loss by occupying space in the stomach." ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, p. 1, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). The figure below, taken from ReShape's instruction manual, shows the dual balloon in a patient's stomach providing modulated passage of food through the gastric cavity upon inflation.



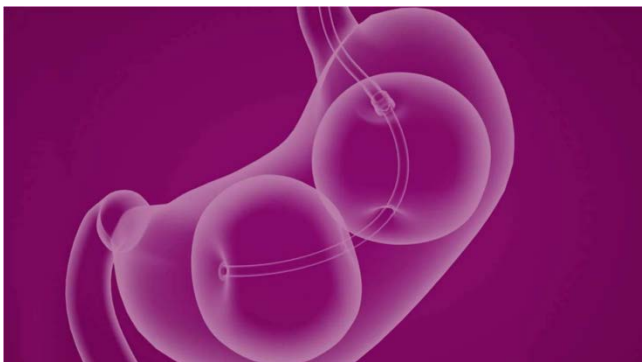
**Figure 1. ReShape Dual Balloon in the Stomach**

54. Claim 4 of the ‘915 patent generally recites the gastric balloon structure of claim 1, wherein, upon inflation, the gastric balloon structure is configured to rest within the gastric cavity without exerting pressure at any point in the gastric cavity sufficient to cause ulceration.

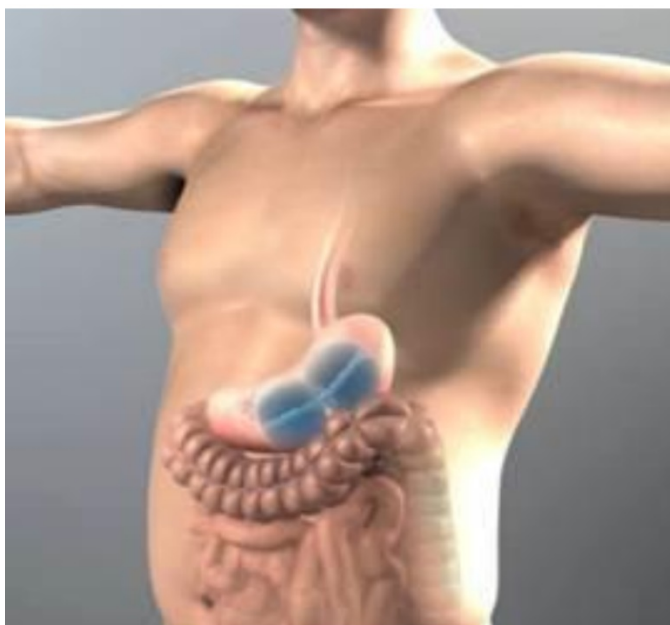
55. The Infringing Instrumentalities infringe claim 4 of the ‘915 patent. The ReShape Dual Balloon mimics “the natural curvature of the stomach, the dual gastric balloon is designed to conform to the patient’s anatomy and enhance tolerability.” *See* <http://pro.reshapeready.com/about-reshape/#theadvantages>. Accordingly, on information and belief, it is configured to rest within the gastric cavity without exerting pressure at any point in the gastric cavity sufficient to cause ulceration.

56. Claim 5 of the ‘915 patent generally recites the gastric balloon structure of claim 4, wherein an outer surface of each of the isolated non-concentric inflatable chambers is configured to align against greater and lesser curvatures of the gastric cavity.

57. The Infringing Instrumentalities infringe claim 5 of the ‘915 patent. The ReShape Dual Balloon mimics “the natural curvature of the stomach, the dual gastric balloon is designed to conform to the patient’s anatomy and enhance tolerability.” *See* <http://pro.reshapeready.com/about-reshape/#theadvantages>.



The conformance of the dual balloon to the stomach of the patient is shown in the image above and is also illustrated in Figure 1 of ReShape’s instructions for use, reproduced below.

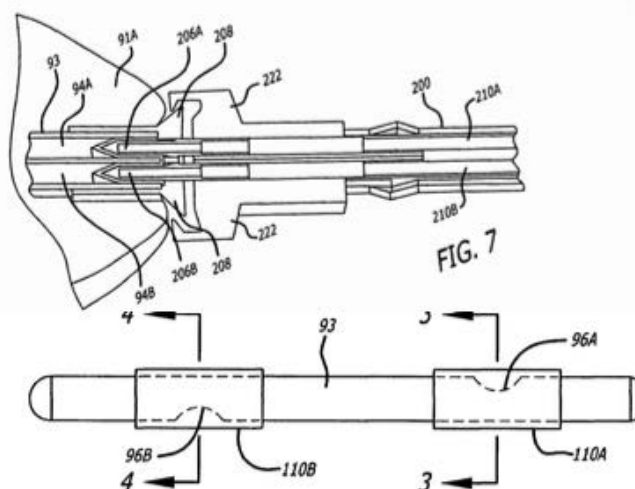


**Figure 1. ReShape Dual Balloon in the Stomach**

Accordingly, on information and belief, an outer surface of each of the isolated non-concentric inflatable chambers is configured to align against greater and lesser curvatures of the gastric cavity.

58. Claim 6 of the ‘915 patent generally recites the gastric balloon structure of claim 1, wherein the valve system comprises a respective valve structure for introducing fluid into each chamber of the at least two isolated non-concentric inflatable chambers, wherein each respective valve structure includes at least two valves in series.

59. Upon information and belief, the Infringing Instrumentalities infringe claim 6 of the ‘915 patent. The chambers of the ReShape balloons are filled after they are positioned in the patient’s stomach. ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, pp. 16-17, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). “The ReShape™ Valve Sealant is necessary to seal the device valves and prevent balloon leakage.” *Id.*; *see also* <https://www.youtube.com/watch?v=U91FsjtMf3o>; Further, ReShape’s patent, U.S. 8,142,469, shows two valves in series as shown below at 206A and 96A:

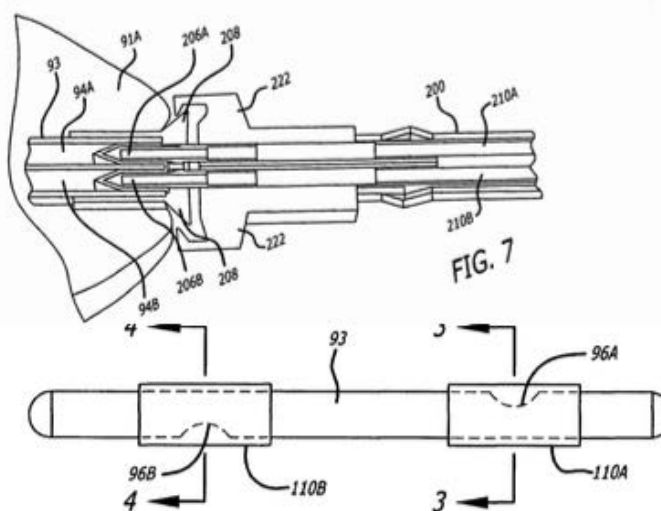


Accordingly, on information and belief, the ReShape Balloon valve system comprises a respective valve structure for introducing fluid into each chamber of the two isolated non-concentric inflatable chambers, wherein each respective valve structure includes at least two valves in series.

60. Claim 7 of the '915 patent generally recites the gastric balloon structure of claim 6, wherein a first valve structure of a first chamber of the at least two isolated non-concentric inflatable chambers includes a one-way valve in series with an additional one-way valve.

61. Upon information and belief, the Infringing Instrumentalities infringe claim 7 of the '915 patent. The chambers of the ReShape balloons are filled after they are positioned in the patient's stomach. ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, pp. 16-17, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). "The ReShape™ Valve Sealant is necessary to seal the device valves and prevent balloon leakage." *Id.*; *see also* <https://www.youtube.com/watch?v=U91FsjtMf3o>; Further, ReShape's patent, U.S. 8,142,469, shows two one-way valves in series as shown below at 206A and 96A:





Accordingly, on information and belief, the ReShape Balloon valve structure includes a one-way valve in series with an additional one-way valve.

62. Claim 8 of the '915 patent generally recites the gastric balloon structure of claim 1, wherein the flexible central spine is in fluid communication with the valve system.

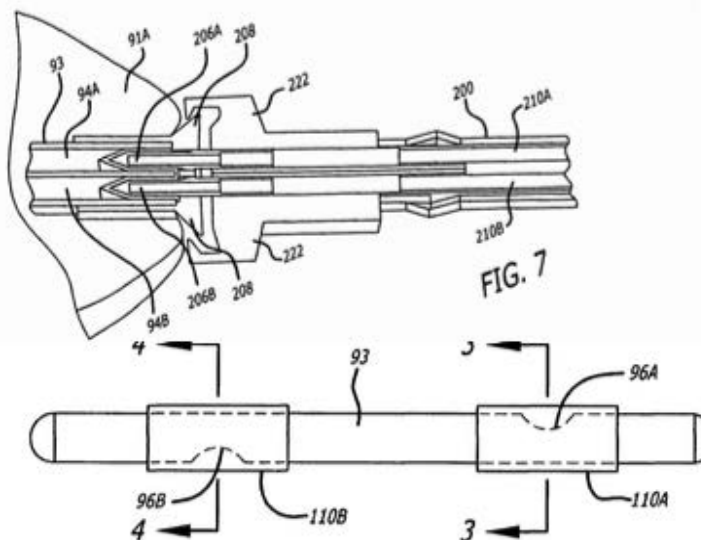
63. Upon information and belief, the Infringing Instrumentalities infringe claim 8 of the '915 patent. The flexible central spine element is illustrated in the video provided on ReShape's website, a frame from which is reproduced below. *See*

<https://reshapeready.com/reshape-cc/>; *see also*

<https://www.youtube.com/watch?v=U91FsjtMf3o>.



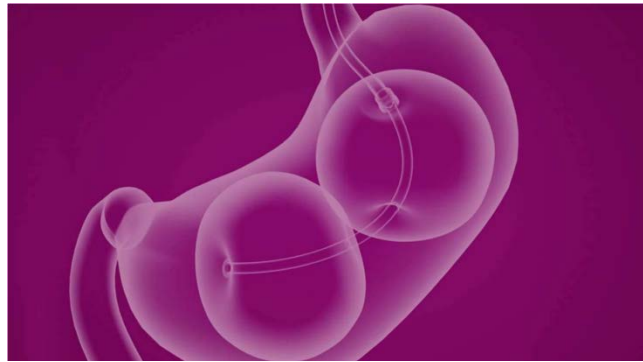
Further, ReShape's patent, U.S. 8,142,469, shows that the inflation lumens and valves are carried by the flexible central spine as shown below:



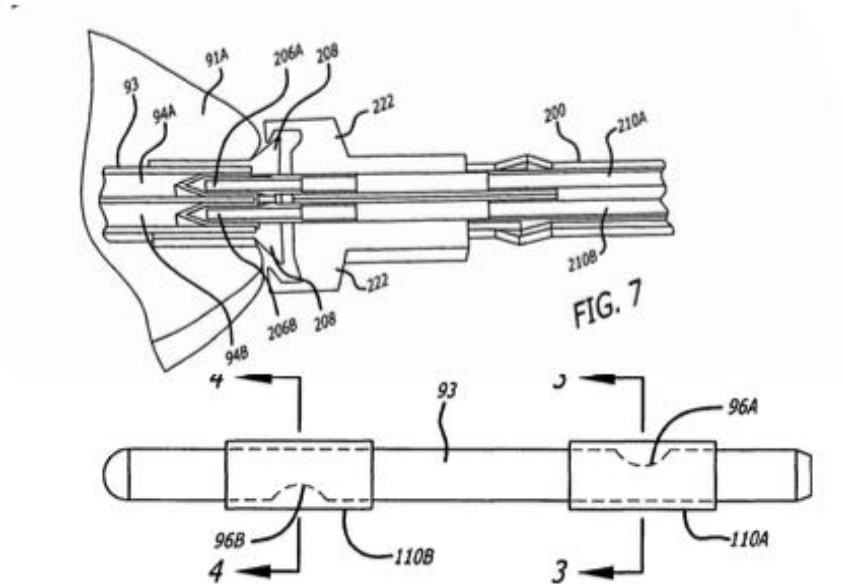
Accordingly, on information and belief, the ReShape Balloon's flexible central spine is in fluid communication with the valve system.

64. Claim 9 of the '915 patent generally recites the gastric balloon structure of claim 8, wherein the flexible central spine encloses an inflation lumen for introducing the fluid into the at least two isolated non-concentric inflatable chambers.

65. Upon information and belief, the Infringing Instrumentalities infringe claim 9 of the '915 patent. The chambers of the ReShape balloons are filled after they are positioned in the patient's stomach. ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, pp. 16-17, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). "The ReShape™ Valve Sealant is necessary to seal the device valves and prevent balloon leakage." *Id.*; see also <https://www.youtube.com/watch?v=U91FsjtMf3o>. The flexible central spine element is illustrated in the video provided on ReShape's website, a frame from which is reproduced below. See <https://reshapeready.com/reshape-cc/>.



Further, ReShape's patent, U.S. 8,142,469, shows that the inflation lumens and valves are carried by the flexible central spine as shown below:



Accordingly, on information and belief, the ReShape Balloon's flexible central spine encloses an inflation lumen for introducing the fluid into the at least two isolated non-concentric inflatable chambers.

66. Claim 10 of the '915 patent generally recites the gastric balloon structure of claim 1, wherein the gastric balloon structure is designed to maintain the introduced volume of fluid while deployed in the gastric cavity of the patient without controlled adjustment.

67. The Infringing Instrumentalities infringe claim 10 of the ‘915 patent. The ReShape dual balloons are both filled with saline and remain at a generally fixed volume until they are removed. See <https://www.youtube.com/watch?v=U91FsjtMf3o>; [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf), Sec. 2.1 – 2.7 at p. 15-16, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf).

68. Claim 11 of the ‘915 patent generally recites the gastric balloon structure of claim 1, wherein each chamber of the at least two isolated non-concentric inflatable chambers is filled with a same fluid.

69. The Infringing Instrumentalities infringe claim 11 of the ‘915 patent. The ReShape dual balloons are both filled with saline and remain at a fixed volume until they are removed. See <https://www.youtube.com/watch?v=U91FsjtMf3o>; [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf), Sec. 2.1 – 2.7 at p. 15-16.

70. Claim 12 of the ‘915 patent recites “a method for treating obesity in a patient, comprising: measuring one or more dimensions of a gastric cavity of the patient in a feeding state . . . .” The ReShape Dual Balloon “is a temporary implant designed to facilitate weight loss by occupying space in the stomach.” ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, p. 1. ReShape’s instructions for use state as follows:

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.

See [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf) at 16. ReShape instructs the user to determine the size of the patient and to select a corresponding fill volume for the balloon structure.

71. Claim 12 of the ‘915 patent further recites “determining, based on the one or more dimensions of the gastric cavity, a respective fill volume for each chamber of a plurality of inflatable-space filling chambers of an obesity treatment device . . . .” ReShape’s instructions for use state as follows:

2.4. Determine the desired inflation volume for each balloon. A fill volume of 375

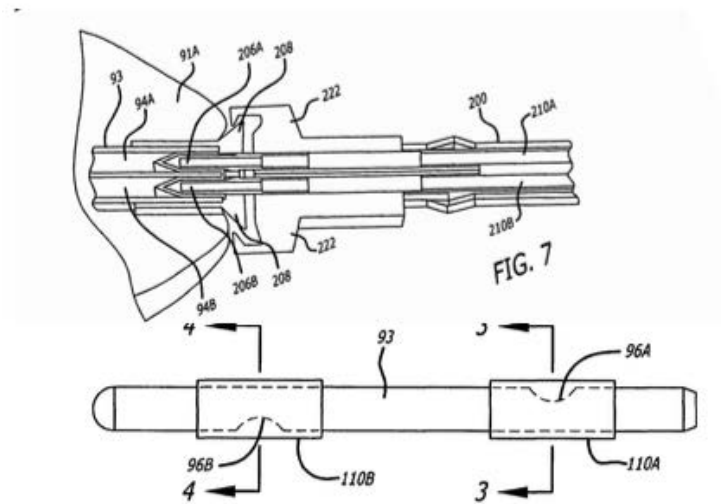
cc is recommended for patients < 64.5” in stature and 450 cc for patients ≥ 64.5” in stature.

See [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf) at

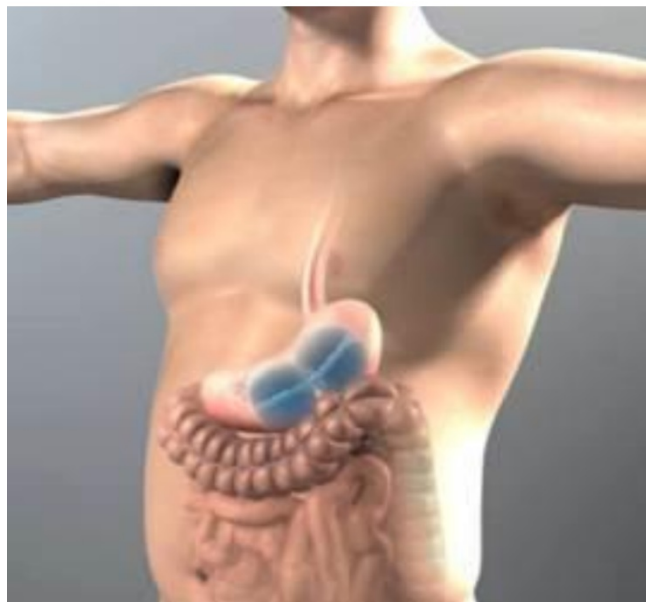
16. ReShape instructs the user to determine the size of the patient and to select a corresponding fill volume for the balloon structure.

72. Claim 12 of the ‘915 patent further recites “positioning the obesity treatment device in the gastric cavity in a deflated state . . . .” The chambers of the ReShape balloons are filled after they are positioned in the patient’s stomach. ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, pp. 16-17, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). “The ReShape™ Valve Sealant is necessary to seal the device valves and prevent balloon leakage.” *Id.*

73. Claim 12 of the ‘915 patent further recites “after positioning, at least partially filling each chamber of a plurality of inflatable space-filling chambers of the obesity treatment device with the respective volume of a same type of fluid via a valve system, wherein the respective volumes of fluid remain unadjusted during treatment[.]” The chambers of the ReShape balloons are filled after they are positioned in the patient’s stomach. ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, pp. 16-17, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). The ReShape dual balloons are both filled with saline and remain at a fixed volume until they are removed. See <https://www.youtube.com/watch?v=U91FsjtMf3o>; [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf), Sec. 2.1 – 2.7 at p. 15-16. “The ReShape™ Valve Sealant is necessary to seal the device valves and prevent balloon leakage.” *Id.*; see also <https://www.youtube.com/watch?v=U91FsjtMf3o> ; Further, ReShape’s patent, U.S. 8,142,469, shows two valves in series as shown below at 206A and 96A:



74. Claim 12 of the '915 patent further recites "wherein the obesity treatment device assumes a natural three-dimensional kidney shape of the gastric cavity such that, upon at least partially filling the chambers, an outer surface of the obesity treatment device aligns against greater and lesser curvatures of the gastric cavity . . . ." The conformance of the dual balloon to the stomach of the patient is shown in the image above and is also illustrated in Figure 1 of ReShape's instructions for use, reproduced below.



**Figure 1. ReShape Dual Balloon in the Stomach**

The ReShape Dual Balloon mimics “the natural curvature of the stomach, the dual gastric balloon is designed to conform to the patient’s anatomy and enhance tolerability.” See <http://pro.reshapeready.com/about-reshape/#theadvantages>.

75. Lastly, claim 12 of the ‘915 patent recites “wherein the obesity treatment device, upon at least partially filling the chambers, rests within the gastric cavity without exerting undue pressure against the gastric cavity at any particular point.” The ReShape Dual Balloon mimics “the natural curvature of the stomach, the dual gastric balloon is designed to conform to the patient’s anatomy and enhance tolerability.” See <http://pro.reshapeready.com/about-reshape/#theadvantages>.

76. Claim 13 of the ‘915 patent generally recites the method of claim 12, further comprising, after treating the obesity: (i) deflating, within the gastric cavity, each chamber of the plurality of inflatable space-filling chambers; and (ii) removing the obesity treatment device.

77. The Infringing Instrumentalities infringe claim 13 of the ‘915 patent. Regarding removal and deflation within the gastric cavity, the ReShape instructions state “continue aspiration until the proximal balloon is completely deflated.” [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf), at p. 18. ReShape Dual Balloons are delivered through endoscopic procedures and “insertion and removal may be completed in an endoscopy suite.” See <http://pro.reshapeready.com/about-reshape/#theadvantages>.

78. Claim 14 of the ‘915 patent generally recites the method of claim 13, wherein removing the obesity treatment device comprises removing the obesity treatment device via an esophagus of the patient.

79. The Infringing Instrumentalities infringe claim 14 of the ‘915 patent. ReShape Dual Balloons are removed via endoscopic procedures and “insertion and removal may be completed in an endoscopy suite.” See <http://pro.reshapeready.com/about-reshape/#theadvantages>.

80. Claim 15 of the ‘915 patent generally recites the method of claim 13, wherein deflating each chamber comprises penetrating each chamber to release the fluid.

81. The Infringing Instrumentalities infringe claim 15 of the ‘915 patent. The ReShape instructions state: “after retracting the needle, advance the catheter through the cut hole until the balloon surface reaches the triple line marker on the tubing” and “continue aspiration until the proximal balloon is completely deflated.” [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf), at p. 18. In other words, deflating each chamber comprises penetrating each chamber to release the fluid.

82. Claim 16 of the ‘915 patent generally recites the method of claim 12, wherein introducing the obesity treatment device inside the gastric cavity comprises introducing the device through an esophagus of the patient.

83. The Infringing Instrumentalities infringe claim 16 of the ‘915 patent. ReShape Dual Balloons are delivered through endoscopic procedures and “insertion and removal may be completed in an endoscopy suite.” See <http://pro.reshapeready.com/about-reshape/#theadvantages>.

84. Claim 17 of the ‘915 patent generally recites the method of claim 12, wherein, upon inflation, the obesity treatment device rests within the gastric cavity without exerting pressure at any point in the gastric cavity sufficient to cause ulceration.

85. The Infringing Instrumentalities infringe claim 17 of the ‘915 patent. The ReShape Dual Balloon mimics “the natural curvature of the stomach, the dual gastric balloon is designed to conform to the patient’s anatomy and enhance tolerability.” See <http://pro.reshapeready.com/about-reshape/#theadvantages>. Accordingly, on information and belief, it is configured to rest within the gastric cavity without exerting pressure at any point in the gastric cavity sufficient to cause ulceration.

86. Claim 18 of the ‘915 patent generally recites the method of claim 12, wherein at least partially filling each chamber comprises: (i) releasably attaching an inflation tube to the valve system; and (ii) introducing the fluid into a first chamber of the plurality of inflatable space-filling chambers through the inflation tube.

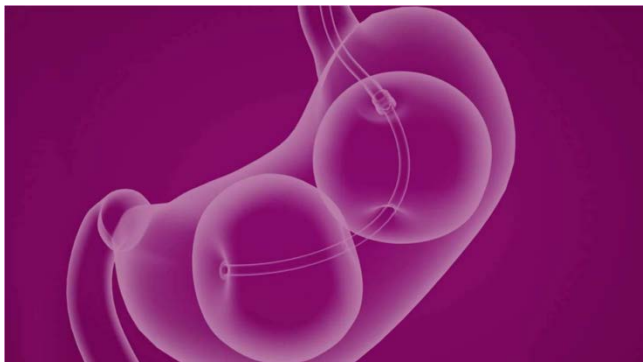
87. The Infringing Instrumentalities infringe claim 18 of the ‘915 patent. The chambers of the ReShape balloons are filled after they are positioned in the patient’s stomach.



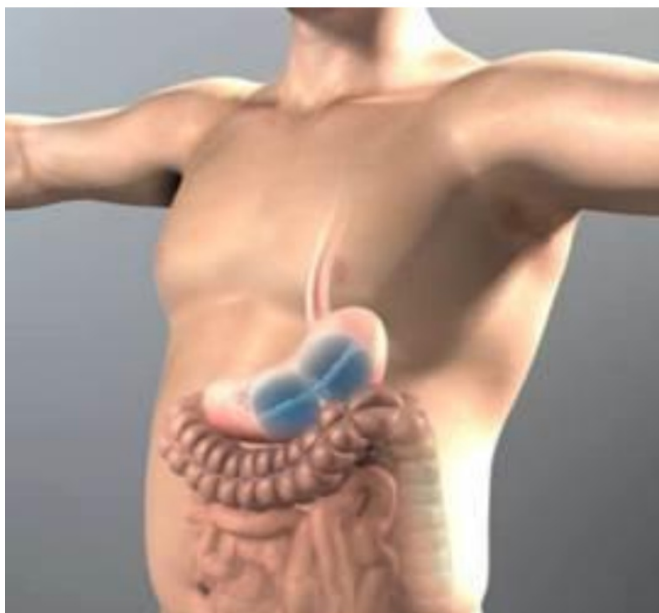
ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, pp. 16-17, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf).

“The ReShape™ Valve Sealant is necessary to seal the device valves and prevent balloon leakage.” *Id.* at 17. Accordingly, on information and belief, the ReShape balloons are filled by releasably attaching an inflation tube to the valve system and introducing the fluid into a first chamber of the inflatable space-filling chambers through the inflation tube.

88. Claim 19 of the ‘915 patent recites “an obesity treatment device for deploying in a stomach of a patient, comprising: a means for occupying an overall space-filling geometry having or conforming to a natural kidney shape of the stomach, upon inflation, by aligning an outer surface of the obesity treatment device against greater and lesser curvatures of the stomach . . . .” The Infringing Instrumentalities infringe claim 19 of the ‘915 patent. The ReShape Dual Balloon “is a temporary implant designed to facilitate weight loss by occupying space in the stomach.” ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, p. 1, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). The video on ReShape’s website shows how the dual balloon structure conforms to the natural curvature and shape of the stomach. <https://reshapeready.com/reshape-cc/>. A frame from that video is reproduced below.



The conformance of the dual balloon to the stomach of the patient is also illustrated in Figure 1 of ReShape’s instructions for use, reproduced below.



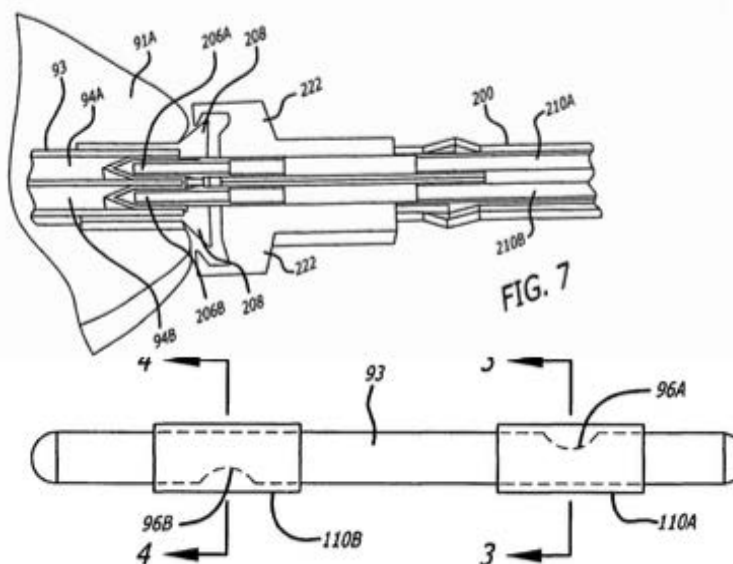
**Figure 1. *ReShape* Dual Balloon in the Stomach**

The *ReShape* Dual Balloon mimics “the natural curvature of the stomach, the dual gastric balloon is designed to conform to the patient’s anatomy and enhance tolerability.” See <http://pro.reshapeready.com/about-reshape/#theadvantages>.

89. Claim 19 of the ‘915 patent further recites “a means for isolating a plurality of inflatable space-filling regions of the overall space-filling geometry such that a collective inflated state volume of the plurality of inflatable space-filling regions remaining inflated after deflation of any single region of the plurality of inflatable space-filling regions prevents the obesity treatment device from passing through a pyloric valve of the stomach . . . .” The introduction of the fluid to the balloons is described at pages 16-17 of the Instructions for Use, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). The *ReShape* website states that “[i]n the unlikely event of individual gastric balloon leakage or deflation, the independently sealed *ReShape* weight loss balloons are designed to minimize risk of migration or obstruction.” <http://pro.reshapeready.com/about-reshape/#theadvantages>. In other words, the dual balloon design will prevent the implant from passing to the patient’s intestinal tract in the event one of the balloons ruptures or otherwise deflates.

90. Claim 19 of the '915 patent further recites “a means for distributing a fluid to the plurality of inflatable space-filling regions comprising a first means for receiving a fluid into a first inflatable space-filling region of the plurality of inflatable space-filling regions and for retaining the fluid in the first inflatable space-filling region, and a second means for receiving the fluid into the first inflatable space-filling region and for retaining the fluid in the first inflatable space-filling region, wherein the first means is provided in series with the second means . . . .”

The chambers of the ReShape balloons are filled after they are positioned in the patient's stomach. ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, pp. 16-17, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). The ReShape dual balloons are both filled with saline and remain at a fixed volume until they are removed. *See* <https://www.youtube.com/watch?v=U91FsjtMf3o>; [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf), Sec. 2.1 – 2.7 at p. 15-16. “The ReShape™ Valve Sealant is necessary to seal the device valves and prevent balloon leakage.” *Id.*; *see also* <https://www.youtube.com/watch?v=U91FsjtMf3o>; Further, ReShape's patent, U.S. 8,142,469, shows two valves in series as shown below at 206A and 96A:



91. Lastly, claim 19 of the ‘915 patent recites “wherein a respective fluid volume for filling each region of the plurality of inflatable space-filling regions to occupy the overall space-filling geometry is selected based upon dimensions of the stomach of the patient.” Reshape’s instructions for use state as follows:

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  $\geq$  64.5” in stature.

See [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf) at

16. ReShape instructs the user to determine the size of the patient and to select a corresponding fill volume for the balloon structure

92. Claim 20 of the ‘915 patent generally recites the obesity treatment device of claim 19, further comprising a means for flexibly connecting at least the first inflatable space-filling region and a second inflatable space-filling region of the plurality of inflatable space-filling regions by spanning a gap between the first inflatable space-filling region and the second inflatable space-filling region, wherein the first inflatable space-filling region is configured to be spaced apart from the second inflatable space-filling region within the stomach along a curved longitudinal axis of the obesity treatment device.

93. The Infringing Instrumentalities infringe claim 20 of the ‘915 patent. The ReShape dual balloons use a flexible spine to connect two gastric balloons. The flexible central spine element is illustrated in the video provided on ReShape’s website, a frame from which is reproduced below. See <https://reshapeready.com/reshape-cc/> ; see also <https://www.youtube.com/watch?v=U91FsjtMf3o> .



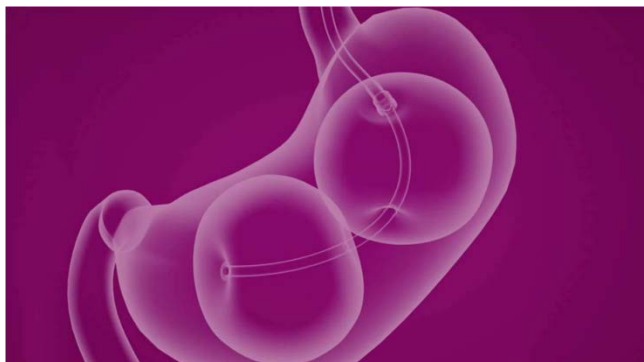
Accordingly, upon information and belief, the ReShape spine flexibly connects at least the first inflatable space-filling region and a second inflatable space-filling region of the plurality of inflatable space-filling regions by spanning a gap between the first inflatable space-filling region and the second inflatable space-filling region, wherein the first inflatable space-filling region is configured to be spaced apart from the second inflatable space-filling region within the stomach along a curved longitudinal axis of the obesity treatment device.

94. Claim 21 of the '915 patent generally recites the obesity treatment device of claim 20, wherein the means for flexibly connecting is in fluid communication with the means for distributing the fluid.

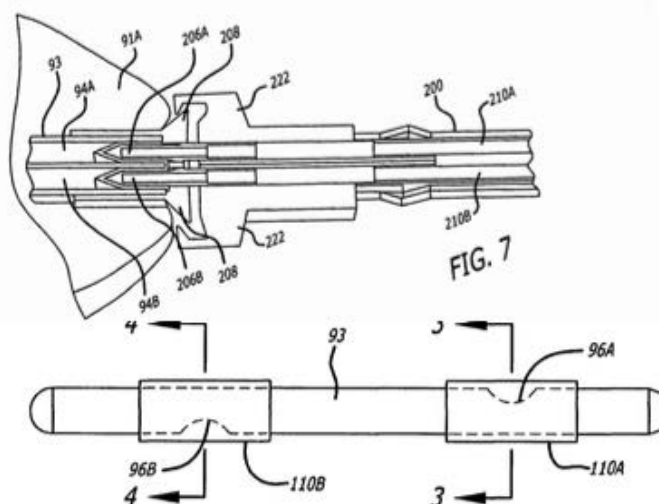
95. Upon information and belief, the Infringing Instrumentalities infringe claim 21 of the '915 patent. The flexible central spine element is illustrated in the video provided on ReShape's website, a frame from which is reproduced below. *See*

<https://reshapeready.com/reshape-cc/>; *see also*

<https://www.youtube.com/watch?v=U91FsjtMf3o>.



Further, ReShape's patent, U.S. 8,142,469, shows that the inflation lumens and valves are carried by the flexible central spine as shown below:



Accordingly, on information and belief, the ReShape balloon's flexible spine is in fluid communication with the means for distributing the fluid.

96. Claim 22 of the '915 patent generally recites the obesity treatment device of claim 20, wherein the means for flexibly connecting is configured to detachably connect, after deploying in the stomach, to a means for introducing the fluid.

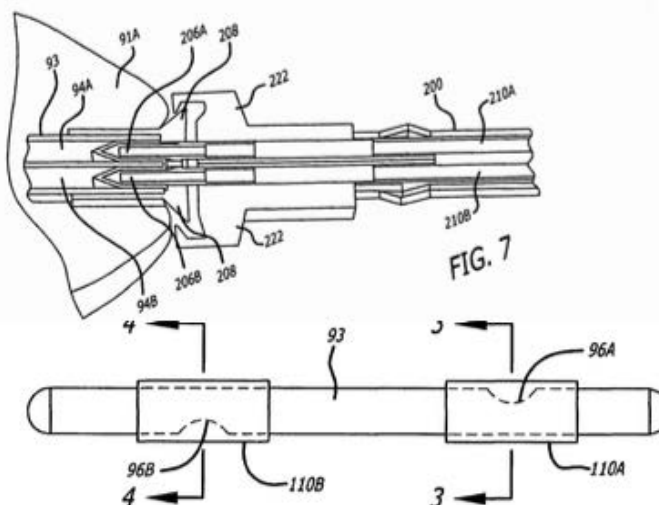
97. Upon information and belief, the Infringing Instrumentalities infringe claim 22 of the '915 patent. The flexible central spine element is illustrated in the video provided on ReShape's website, a frame from which is reproduced below. *See*

<https://reshapeready.com/reshape-cc/>; *see also*

<https://www.youtube.com/watch?v=U91FsjtMf3o>.



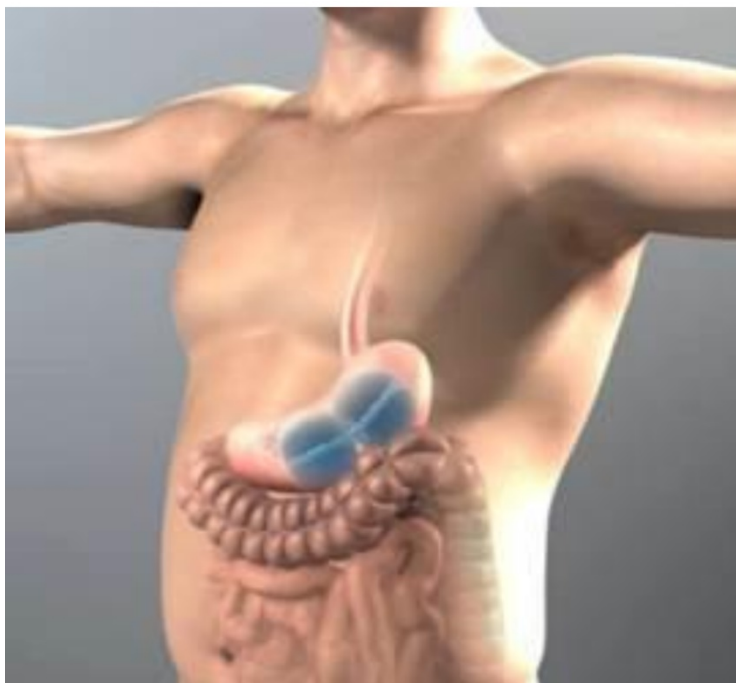
Further, ReShape's patent, U.S. 8,142,469, shows that the inflation lumens and valves are carried by the flexible central spine as shown below:



Accordingly, on information and belief, the ReShape balloon's flexible spine is configured to detachably connect, after deploying in the stomach, to a means for introducing the fluid.

98. Claim 23 of the '915 patent generally recites the obesity treatment device of claim 19, wherein the means for occupying the overall space-filling geometry provides for modulated passage of food through the stomach.

99. The Infringing Instrumentalities infringe claim 23 of the '915 patent. The ReShape Dual Balloon "is a temporary implant designed to facilitate weight loss by occupying space in the stomach." ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, p. 1, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). The figure below, taken from ReShape's instruction manual, shows the dual balloon in a patient's stomach providing modulated passage of food through the stomach.



**Figure 1. *ReShape* Dual Balloon in the Stomach**

100. Claim 24 of the '915 patent generally recites the obesity treatment device of claim 19, wherein the means for occupying the overall space-filling geometry delineates a space along a curved longitudinal axis of the obesity treatment device distal to the gastro-esophageal junction for the collection of ingested food and another space proximal to the pyloric valve for active digestion.

101. The Infringing Instrumentalities infringe claim 24 of the '915 patent. The images below from ReShape's website and instruction manual, found at <https://reshapeready.com/reshape-cc/> and ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, p. 1, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf), respectively, demonstrate the geometry required to satisfy this element.



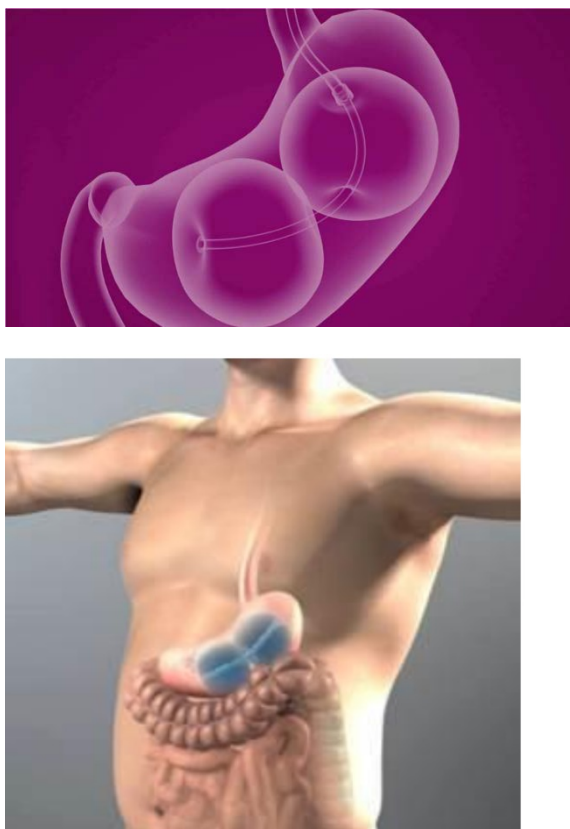


Figure 1. *ReShape* Dual Balloon in the Stomach

Accordingly, on information and belief, the *ReShape* Balloon delineates a space along a curved longitudinal axis of the obesity treatment device distal to the gastro-esophageal junction for the collection of ingested food and another space proximal to the pyloric valve for active digestion.

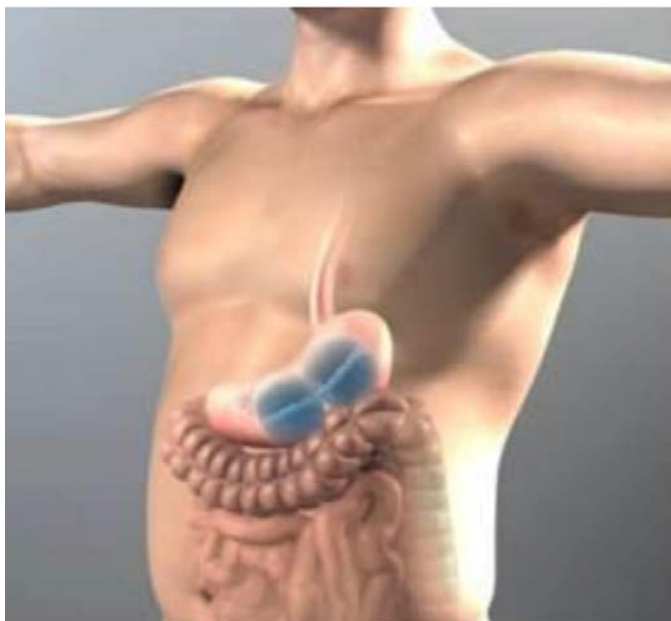
102. Claim 25 of the ‘915 patent generally recites the obesity treatment device of claim 19, wherein the means for occupying the overall space-filling geometry is configured such that, upon inflation, the obesity treatment device rests within the gastric cavity without exerting pressure at any point in the stomach sufficient to cause ulceration.

103. The Infringing Instrumentalities infringe claim 25 of the ‘915 patent. The *ReShape* Dual Balloon mimics “the natural curvature of the stomach, the dual gastric balloon is designed to conform to the patient’s anatomy and enhance tolerability.” *See* <http://pro.reshapeready.com/about-reshape/#theadvantages>. Accordingly, on information and

belief, it is configured to rest within the gastric cavity without exerting pressure at any point in the gastric cavity sufficient to cause ulceration.

104. Claim 26 of the '915 patent generally recites the obesity treatment device of claim 19, wherein the obesity treatment device is configured to be untethered in the stomach after inflation.

105. The Infringing Instrumentalities infringe claim 26 of the '915 patent. The following images below from ReShape's website and instruction manual demonstrate that a tether is not used in the ReShape Balloon System. *See generally* <https://reshapeready.com/reshape-cc/>; ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, p. 1, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf).



**Figure 1. ReShape Dual Balloon in the Stomach**

106. Claim 27 of the '915 patent generally recites the obesity treatment device of claim 19, wherein the respective fluid volume of each region of the plurality of inflatable space-filling regions contains a same type of fluid.

107. The Infringing Instrumentalities infringe claim 27 of the '915 patent. The ReShape dual balloons are both filled with saline and remain at a fixed volume until they are removed. See <https://www.youtube.com/watch?v=U91FsjtMf3o>; [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf), Sec. 2.1 – 2.7 at p. 15-16.

108. On information and belief, the Infringing Instrumentalities are used marketed, provided to, and/or used by or for the Infringing ReShape Entities' partners, clients, customers and end users across the country and in this District.

109. SV Health's infringement of the '915 patent has been, and continues to be knowing, intentional, and willful, in whole or in part because SV Health has been aware of the '915 patent since its issuance and continue to engage in infringing conduct. SV Health, through its control of the Infringing ReShape Entities had knowledge of all major aspects of Fulfillium's business plans, including trade secrets divulged pursuant to an oral agreement of confidentiality. SV Health through its control of the Infringing ReShape Entities knew that Fulfillium was actively engaged in patenting its gastric balloon technology. Further, SV Health through its control of the Infringing ReShape Entities was fully aware that its technology would copy many aspects of Dr. Chen's inventions because it was developed after and with knowledge of Dr. Chen's designs. The fact that ReShape Medical, Inc. knew of Dr. Chen's patents and believed those patents to be relevant to ReShape Medical, Inc.'s gastric balloon technology is demonstrated by ReShape Medical Inc.'s citation of Dr. Chen's patents as relevant prior art when attempting to procure its own patents. For instance, in December 2012 ReShape Medical, Inc. filed an information disclosure statement with the United States Patent and Trademark Office indicating that Dr. Chen's previous patent applications were relevant to ReShape Medical, Inc.'s pending patent application directed to the ReShape Balloon. Upon information and belief SV Health actively directed or could have directed ReShape Medical, Inc. to file patent applications covering its gastric balloon technology.

110. On information and belief, SV Health through its control of the Infringing ReShape Entities has been aware of the existence of the ‘915 patent since its issuance.

111. Upon information and belief, since at least the SV Health had been made aware of the ‘915 patent, it has induced and continues to induce others to infringe at least one claim of the ‘915 patent under 35 U.S.C. § 271(b) by, among other things, and with specific intent or willful blindness, actively aiding and abetting others to infringe, including but not limited to the Infringing ReShape Entities infringe at least one claim of the ‘915 patent.

112. Fulfillium has suffered and will continue to suffer damages as a result of SV Health’s infringing activities. On information and belief, SV Health has infringed, and will, unless enjoined by this Court, continue to infringe the ‘915 patent by inducing and/or actively aiding and abetting the Infringing ReShape Entities to make, use, sell, offer to sell, and/or import, at a minimum, the ReShape Duo Balloon.

113. Each of SV Health’s acts of infringement of the ‘915 patent have caused and will continue to cause Fulfillium damages for which Fulfillium is entitled to compensation pursuant to 35 U.S.C. § 284.

114. Each of SV Health’s acts of infringement of the ‘915 patent have caused and will continue to cause Fulfillium immediate and irreparable harm unless such infringing activities are enjoined by this Court pursuant to 35 U.S.C. § 283. Fulfillium has no adequate remedy at law.

115. This case is exceptional and, therefore, Fulfillium is entitled to an award of attorneys’ fees pursuant to 35 U.S.C. § 285.

**COUNT II – INFRINGEMENT OF U.S. PATENT NO. 9,445,930**

116. Fulfillium repeats the allegations of paragraphs 1-115 above as though fully set forth herein.

117. On September 20, 2016, U.S. Patent No. 9,445,930 (“the ‘930 patent”), entitled “Methods, Devices, and Systems for Obesity Treatment,” was duly and legally issued by the United States Patent and Trademark Office. A true and correct copy of the ‘930 patent is attached as Exhibit 2.

118. Fulfillium is the assignee and owner of the right, title and interest in and to the ‘930 patent, including the right to assert all causes of action arising under said patents and the right to any remedies for infringement of them by at least an assignment dated July 17 2018. Ex. A.

119. On information and belief, the Infringing ReShape Entities are engaged in the business of making, using, selling, offering to sell, and/or importing medical devices. A description of ReShape Lifesciences’ business is available on its business website, which is located at <http://pro.reshapeready.com>; <https://reshapeready.com/> .

120. As part of its business, the Infringing ReShape Entities make, use, offer to sell, sell, and/or import a dual intragastric balloon for weight loss, including ReShape Medical’s “Duo Balloon” device, which is placed inside the patient’s stomach for weight loss. The Infringing ReShape Entities have purposefully sold and offered for sale such Duo Balloon devices throughout the United States.

121. Upon information and belief, the Infringing ReShape Entities have and continue to directly infringe at least claims 1-2, 4-19, 21-27, and 30 of the ‘930 patent by making, using, selling, importing and/or providing and causing to be used medical devices for weight loss, including but not limited to, those sold under the name ReShape Duo Balloon (the “Infringing Instrumentalities”)

122. Upon information and belief, SV Health has and continues to indirectly infringe at least claims 1-2, 4-19, 21-27, and 30 of the ‘930 patent by, among other things, and with specific intent or willful blindness, actively aiding and abetting the Infringing ReShape Entities to directly infringe at least claims 1-2, 4-19, 21-27, and 30 of the ‘930 patent by the Infringing ReShape Entities sale of the Infringing Instrumentalities.

123. Upon information and belief, SV Health controls or has controlled a substantial portion of the day to day business activities of the Infringing ReShape Entities.

124. Claim 1 of the ‘930 patent generally recites “An obesity treatment device for deploying in a stomach of a patient, comprising: a plurality of adjacent, spaced apart inflatable space-filling compartments, wherein each compartment of the plurality of inflatable space-filling

compartments has a respective inflated state volume that is maintained during treatment of the patient . . . .” The Infringing Instrumentalities infringe claim 1 of the ‘930 patent. The ReShape Dual Balloon “is a temporary implant designed to facilitate weight loss by occupying space in the stomach.” ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, p. 1, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). The figure below, taken from ReShape’s instruction manual, shows the dual balloon in a patient’s stomach. The ReShape website states that “[i]n the unlikely event of individual gastric balloon leakage or deflation, the independently sealed *ReShape* weight loss balloons are designed to minimize risk of migration or obstruction.” <http://pro.reshapeready.com/about-reshape/#theadvantages>. In other words, each balloon inflates and deflates independently and its inflated volume is maintained. *See also* <https://www.youtube.com/watch?v=U91FsjtMf3o>.

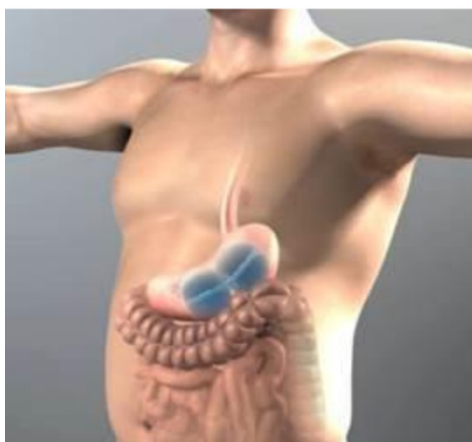
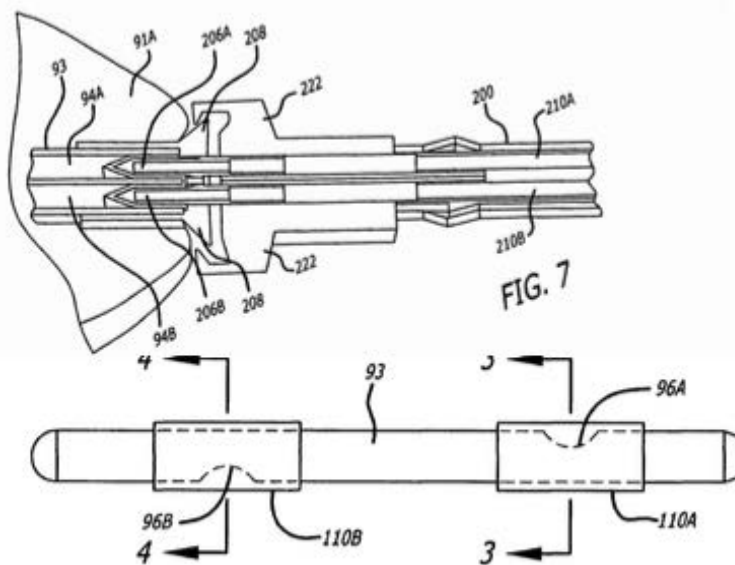


Figure 1. *ReShape* Dual Balloon in the Stomach

125. Claim 1 of the ‘930 patent further recites “a valve system for introducing a fluid into each compartment of the plurality of inflatable space-filling compartments and for retaining, upon inflation, fluid in the plurality of inflatable space-filling compartments . . . .” The chambers of the ReShape balloons are filled after they are positioned in the patient’s stomach. ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, pp. 16-17, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). “The ReShape™ Valve Sealant is necessary to seal the device valves and prevent balloon

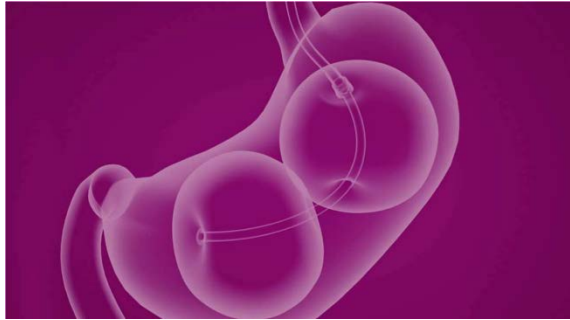
leakage.” *Id.*; see also <https://www.youtube.com/watch?v=U91FsjtMf3o>; U.S. Pat. No. 8,142,469 at Fig. 1, 3-5.

126. Claim 1 of the ‘930 patent further recites “the valve system comprises a respective valve structure for introducing fluid into each inflatable space-filling compartment of the plurality of inflatable space-filling compartments, wherein each respective valve structure includes at least a first valve in series with a second valve . . . .” The chambers of the ReShape balloons are filled after they are positioned in the patient’s stomach. ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, pp. 16-17, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). “The ReShape™ Valve Sealant is necessary to seal the device valves and prevent balloon leakage.” *Id.*; see also <https://www.youtube.com/watch?v=U91FsjtMf3o>; Further, ReShape’s patent, U.S. 8,142,469, shows two valves in series as shown below at 206A and 96A:

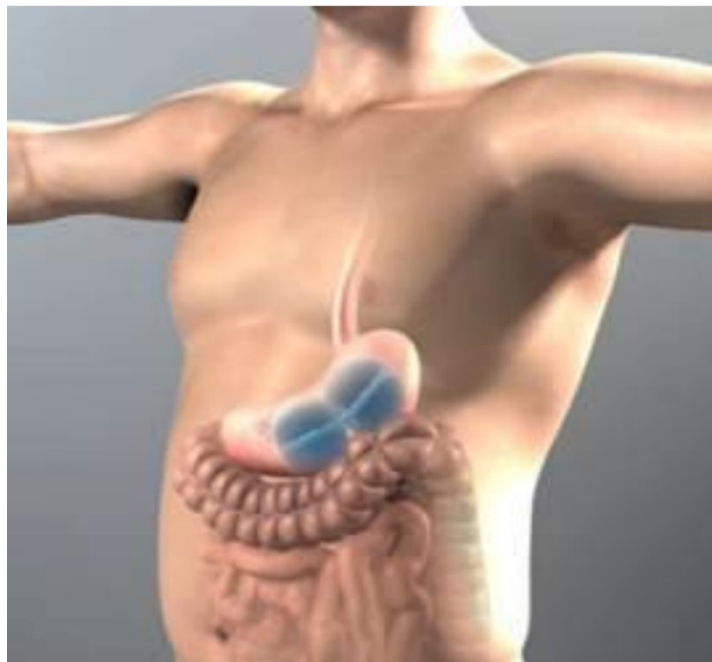


127. Lastly, claim 1 of the ‘930 patent recites “wherein the obesity treatment device is to form, upon at least partially filling the plurality of inflatable space-filling compartments, to a curved shape conforming to a natural three-dimensional kidney shape of the stomach such that an outer surface of the obesity treatment device aligns against greater and lesser curvatures of the

stomach.” The video on ReShape’s website shows how the dual balloon structure conforms to the natural curvature of the stomach. <https://reshapeready.com/reshape-cc/>. A frame from that video is reproduced below.



The conformance of the dual balloon to the stomach of the patient is also illustrated in Figure 1 of ReShape’s instructions for use, reproduced below.



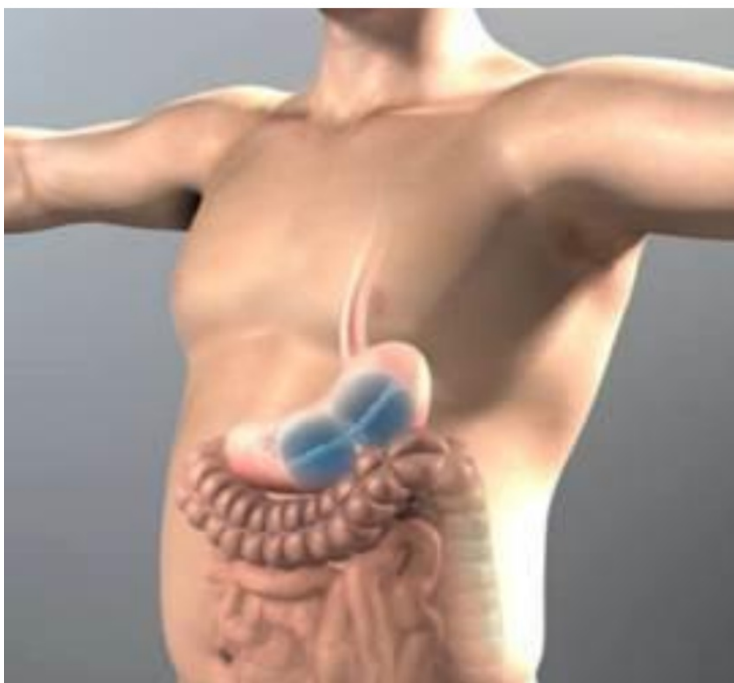
**Figure 1. *ReShape* Dual Balloon in the Stomach**

The ReShape Dual Balloon mimics “the natural curvature of the stomach, the dual gastric balloon is designed to conform to the patient’s anatomy and enhance tolerability.” See <http://pro.reshapeready.com/about-reshape/#theadvantages>.



128. Claim 2 of the '930 patent generally recites the obesity treatment device of claim 1, wherein the plurality of inflatable space-filling compartments form, when in an inflated state, a cavity therebetween through which food may pass.

129. The Infringing Instrumentalities infringe claim 2 of the '930 patent. The ReShape Dual Balloon "is a temporary implant designed to facilitate weight loss by occupying space in the stomach." ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, p. 1, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). The figure below, taken from ReShape's instruction manual, shows the dual balloon in a patient's stomach forming a cavity through which food may pass upon inflation.



**Figure 1. ReShape Dual Balloon in the Stomach**

130. Claim 4 of the '930 patent generally recites the obesity treatment device of claim 1, wherein, upon inflation, the obesity treatment device rests within the stomach without exerting pressure at any point in the stomach sufficient to cause ulceration.

131. The Infringing Instrumentalities infringe claim 4 of the '930 patent. The ReShape Dual Balloon mimics "the natural curvature of the stomach, the dual gastric balloon is designed

to conform to the patient's anatomy and enhance tolerability." See

<http://pro.reshapeready.com/about-reshape/#theadvantages>. Accordingly, on information and belief, it is configured to rest within the gastric cavity without exerting pressure at any point in the gastric cavity sufficient to cause ulceration.

132. Claim 5 of the '930 patent generally recites the obesity treatment device of claim 1, wherein an outer surface of each of the inflatable space-filling compartments aligns against greater and lesser curvatures of the stomach.

133. The Infringing Instrumentalities infringe claim 5 of the '930 patent. The ReShape Dual Balloon mimics "the natural curvature of the stomach, the dual gastric balloon is designed to conform to the patient's anatomy and enhance tolerability." See <http://pro.reshapeready.com/about-reshape/#theadvantages>.



The conformance of the dual balloon to the stomach of the patient is shown in the image above and is also illustrated in Figure 1 of ReShape's instructions for use, reproduced below.

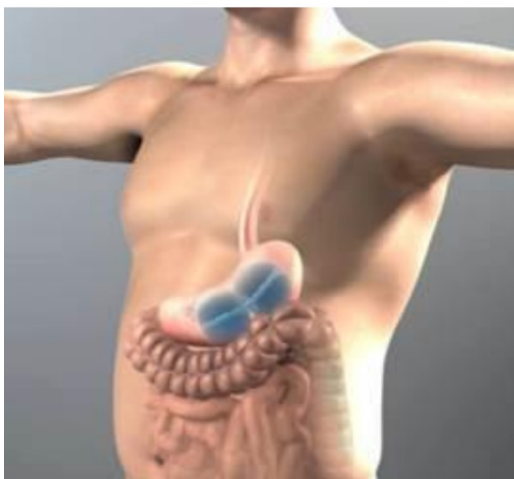


Figure 1. *ReShape* Dual Balloon in the Stomach

Accordingly, on information and belief, an outer surface of each of the inflatable space filling compartments is configured to align against greater and lesser curvatures of the stomach.

134. Claim 6 of the '930 patent generally recites the obesity treatment device of claim 5, wherein the obesity treatment device is untethered in the stomach after inflation.

135. The Infringing Instrumentalities infringe claim 6 of the '930 patent. The following images below from ReShape's website and instruction manual demonstrate that the ReShape Balloon is untethered in the stomach after inflation. *See generally* <https://reshapeready.com/reshape-cc/>; ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, p. 1, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf).

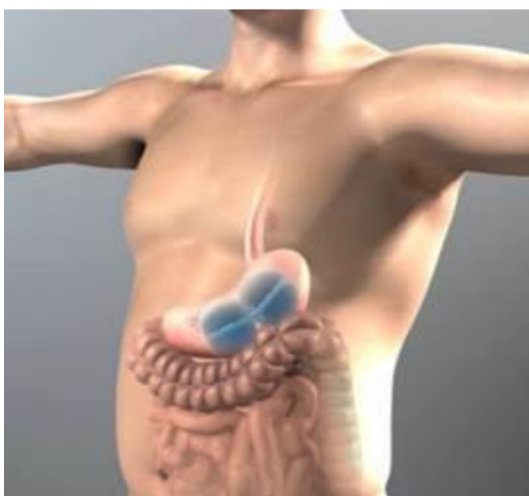
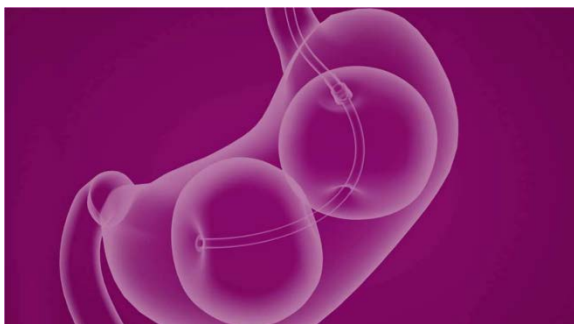
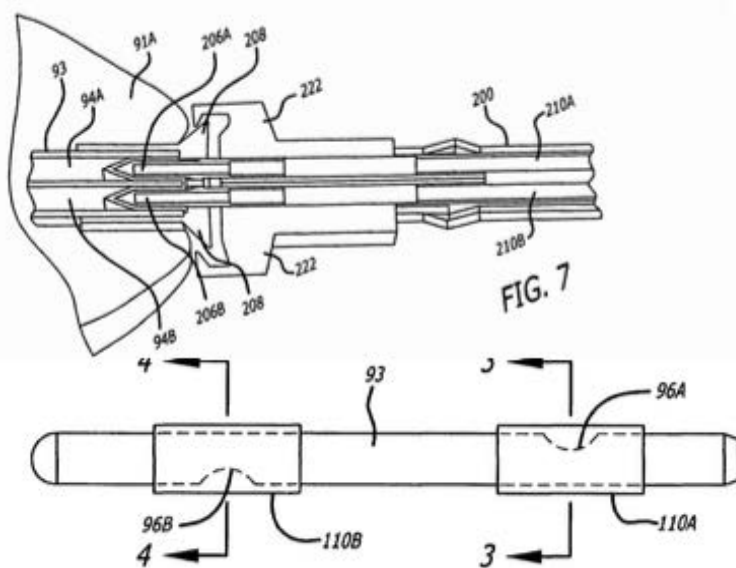


Figure 1. *ReShape* Dual Balloon in the Stomach

136. Claim 7 of the '930 patent generally recites the obesity treatment device of claim 1, wherein the first valve structure includes a one-way valve.

137. Upon information and belief, the Infringing Instrumentalities infringe claim 7 of the '930 patent. The chambers of the ReShape balloons are filled after they are positioned in the patient's stomach. ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, pp. 16-17, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). "The ReShape™ Valve Sealant is necessary to seal the device valves and prevent balloon leakage." *Id.*; see also <https://www.youtube.com/watch?v=U91FsjtMf3o>. Further, ReShape's patent, U.S. 8,142,469, shows a one-way valves as shown below at 206A and 96A:

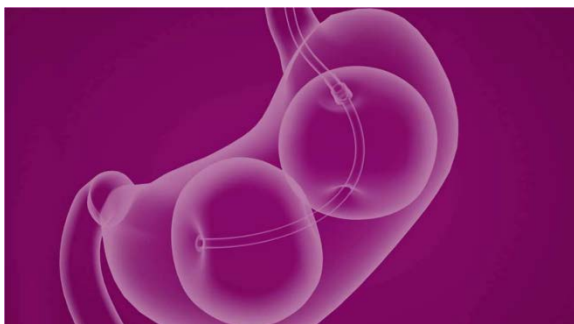


Accordingly, on information and belief, the ReShape Balloon's first valve structure includes a one-way valve.

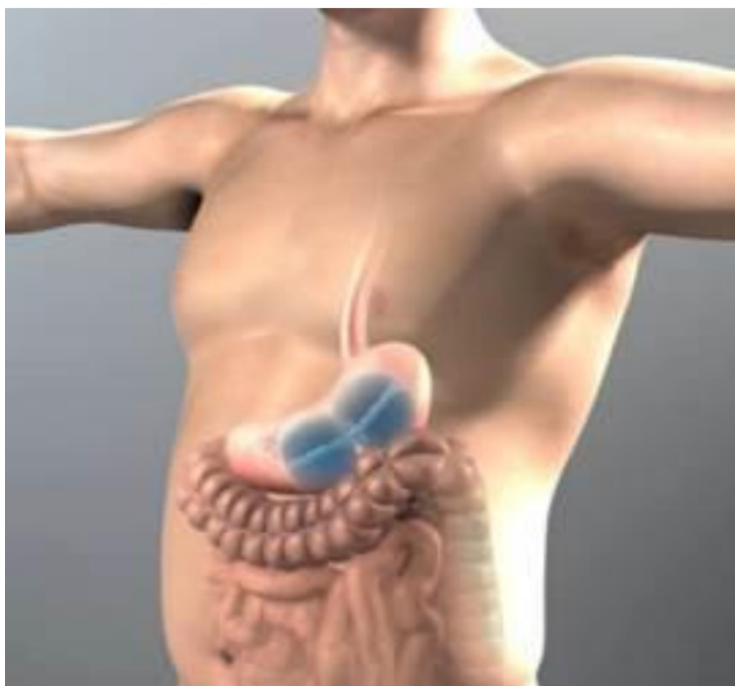
138. Claim 8 of the '930 patent generally recites the obesity treatment device of claim 1, further comprising a flexible central spine structure spanning a gap between and connecting at least a first compartment of the plurality of inflatable space-filling compartments and a second compartment of the plurality of inflatable space-filling compartments, wherein aligning the outer

surface of the obesity treatment device against the greater and lesser curvatures of the stomach comprises flexibly conforming the obesity treatment device to the natural three dimensional kidney shape of the stomach through flexing the flexible central spine structure.

139. The Infringing Instrumentalities infringe claim 8 of the '930 patent. The flexible central spine element is illustrated in the video provided on ReShape's website, a frame from which is reproduced below. See <https://reshapeready.com/reshape-cc/>; see also <https://www.youtube.com/watch?v=U91FsjtMf3o>.



The conformance of the dual balloon to the stomach of the patient is shown in the image above and is also illustrated in Figure 1 of ReShape's instructions for use, reproduced below.



**Figure 1. *ReShape* Dual Balloon in the Stomach**

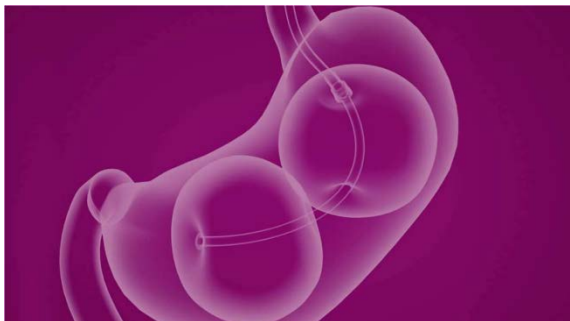
Accordingly, on information and belief, the ReShape Balloon's flexible central spine structure spans a gap between and connects at least a first compartment of the plurality of inflatable space-filling compartments and a second compartment of the plurality of inflatable space-filling compartments, wherein aligning the outer surface of the obesity treatment device against the greater and lesser curvatures of the stomach comprises flexibly conforming the obesity treatment device to the natural three dimensional kidney shape of the stomach through flexing the flexible central spine structure.

140. Claim 9 of the '930 patent generally recites the obesity treatment device of claim 8, wherein the flexible central spine structure is in fluid communication with the valve system.

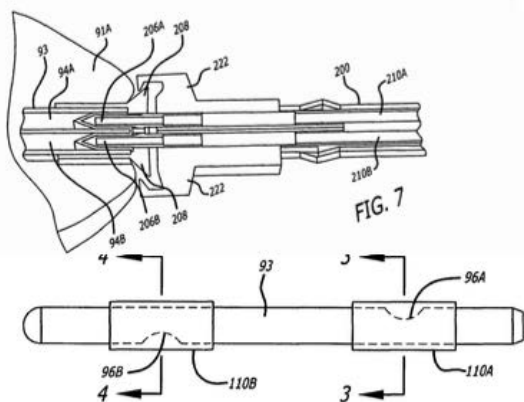
141. Upon information and belief, the Infringing Instrumentalities infringe claim 9 of the '930 patent. The flexible central spine element is illustrated in the video provided on ReShape's website, a frame from which is reproduced below. *See*

<https://reshapeready.com/reshape-cc/>; *see also*

<https://www.youtube.com/watch?v=U91FsjtMf3o>.



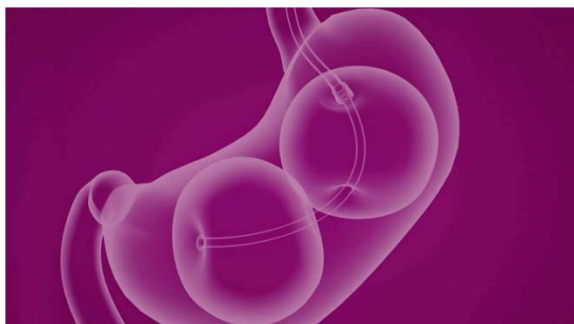
Further, ReShape's patent, U.S. 8,142,469, shows that the inflation lumens and valves are carried by the flexible central spine as shown below:



Accordingly, on information and belief, the ReShape Balloon's flexible central spine structure is in fluid communication with the valve system.

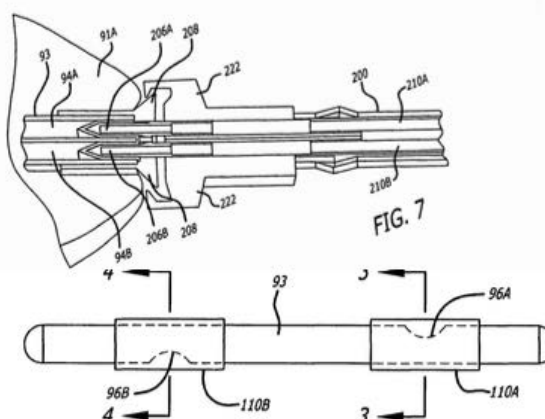
142. Claim 10 of the '930 patent generally recites the obesity treatment device of claim 9, wherein the flexible central spine structure encloses an inflation lumen for introducing the fluid into the plurality of inflatable space-filling compartments.

143. Upon information and belief, the Infringing Instrumentalities infringe claim 10 of the '930 patent. The flexible central spine element is illustrated in the video provided on ReShape's website, a frame from which is reproduced below. *See* <https://reshapeready.com/reshape-cc/>; *see also* <https://www.youtube.com/watch?v=U91FsjtMf3o>.



Further, ReShape's patent, U.S. 8,142,469, shows that the inflation lumens and valves are carried by the flexible central spine as shown below:





Accordingly, on information and belief, the ReShape Balloon's flexible central spine structure encloses an inflation lumen for introducing the fluid into the plurality of inflatable space-filling compartments.

144. Claim 11 of the '930 patent generally recites the obesity treatment device of claim 1, wherein fluid in each of the plurality of inflatable space-filling compartments is a same type of fluid.

145. The Infringing Instrumentalities infringe claim 11 of the '930 patent. The ReShape dual balloons are both filled with saline and remain at a fixed volume until they are removed. See <https://www.youtube.com/watch?v=U91FsjtMf3o>; [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf), Sec. 2.1 – 2.7 at p. 15-16.

146. Claim 12 of the '930 patent recites a “method for deploying a gastric balloon structure in a gastric cavity of a patient.” The ReShape Dual Balloon “is a temporary implant designed to facilitate weight loss by occupying space in the stomach.” ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, p. 1, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). The figure below, taken from ReShape's instruction manual, shows the dual balloon in a patient's stomach.



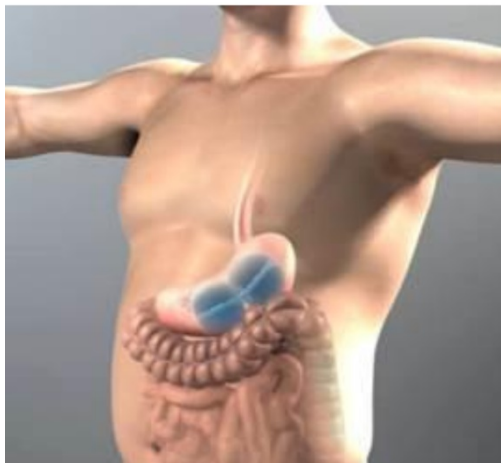


Figure 1. ReShape Dual Balloon in the Stomach

147. Claim 12 of the ‘930 patent further recites the steps of “determining one or more dimensions of the gastric cavity in a feeding state” and “selecting a respective fill volume for each chamber of a plurality of isolated chambers of the gastric balloon structure.” Reshape’s instructions for use state as follows:

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  $\geq$  64.5” in stature.

See [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf) at

16. ReShape instructs the user to determine the size of the patient and to select a corresponding fill volume for the balloon structure.

148. Claim 12 of the ‘930 patent further recites “introducing the gastric balloon structure to the gastric cavity; and after said introducing, at least partially filling each chamber of the plurality of isolated chambers of the gastric balloon structure with the respective volume of fluid via a valve system of the gastric balloon structure.” The chambers of the ReShape balloons are filled after they are positioned in the patient’s stomach. ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, pp. 16-17, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). “The ReShape™ Valve Sealant is necessary to seal the device valves and prevent balloon leakage.” *Id.* at 17.

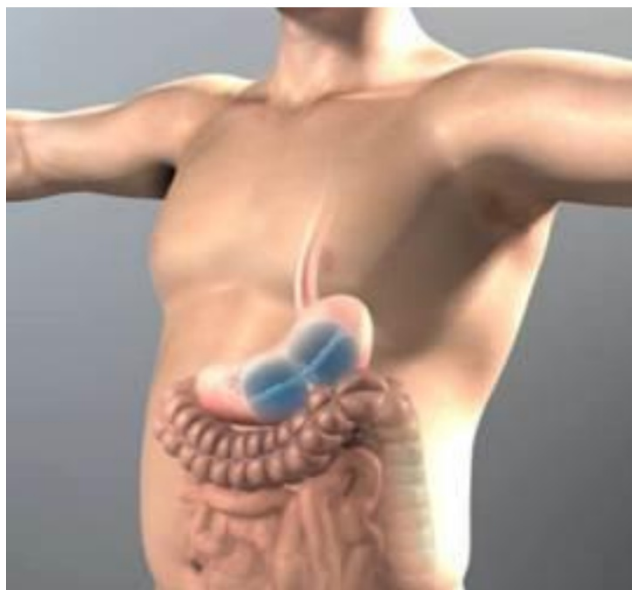
149. Claim 12 of the ‘930 patent further recites that “the plurality of isolated chambers are non-concentric and adjacent, at least partially filling each chamber of the plurality of isolated

chambers comprises introducing fluid into the respective chamber via a respective valve structure of the valve system, and a collective volume of the plurality of isolated chambers remaining inflated after deflation of any single chamber of the plurality of isolated chambers prevents the gastric balloon structure from passing through the pyloric valve of the gastric cavity.” Figure 1 of the Instructions for Use shows that the ReShape balloon has two nonconcentric and adjacent chambers. The introduction of the fluid to the balloons is described at pages 16-17 of the Instructions for Use, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). The ReShape website states that “[i]n the unlikely event of individual gastric balloon leakage or deflation, the independently sealed *ReShape* weight loss balloons are designed to minimize risk of migration or obstruction.” <http://pro.reshapeready.com/about-reshape/#theadvantages>. In other words, the dual balloon design will prevent the implant from passing to the patient’s intestinal tract in the event one of the balloons ruptures.

150. Claim 12 of the ‘930 patent further recites that “the gastric balloon structure, in its inflated state, is to form to a curved shape conforming to a natural three-dimensional kidney shape of the gastric cavity such that an outer surface of the gastric balloon structure aligns against greater and lesser curvatures of the gastric cavity.” The video on ReShape’s website shows how the dual balloon structure conforms to the natural curvature of the stomach. <https://reshapeready.com/reshape-cc/>. A frame from that video is reproduced below.



The conformance of the dual balloon to the stomach of the patient is also illustrated in Figure 1 of ReShape’s instructions for use, reproduced below.



**Figure 1. ReShape Dual Balloon in the Stomach**

151. Claim 13 of the '930 patent generally recites the method of claim 12, wherein the gastric balloon structure, upon inflation, rests within the gastric cavity without exerting pressure at any point in the gastric cavity sufficient to cause ulceration.

152. The Infringing Instrumentalities infringe claim 13 of the '930 patent. The ReShape Dual Balloon mimics “the natural curvature of the stomach, the dual gastric balloon is designed to conform to the patient’s anatomy and enhance tolerability.” *See* <http://pro.reshapeready.com/about-reshape/#theadvantages>. Accordingly, on information and belief, it is configured to rest within the gastric cavity without exerting pressure at any point in the gastric cavity sufficient to cause ulceration.

153. Claim 14 of the '930 patent generally recites the method of claim 12, wherein an outer surface of each one of the space-filling compartments aligns against greater and lesser curvatures of the stomach.

154. The Infringing Instrumentalities infringe claim 14 of the '930 patent. The ReShape Dual Balloon mimics “the natural curvature of the stomach, the dual gastric balloon is designed to conform to the patient’s anatomy and enhance tolerability.” *See* <http://pro.reshapeready.com/about-reshape/#theadvantages>.



The conformance of the dual balloon to the stomach of the patient is shown in the image above and is also illustrated in Figure 1 of ReShape's instructions for use, reproduced below.

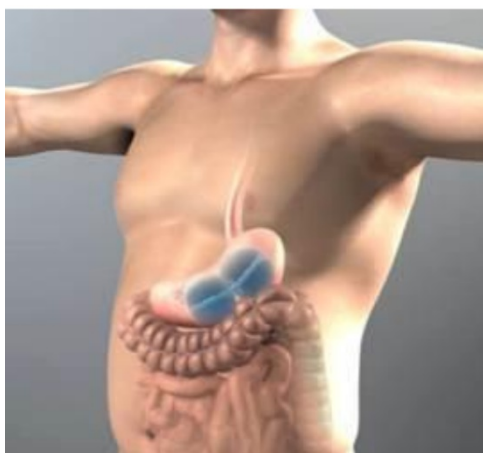


Figure 1. *ReShape* Dual Balloon in the Stomach

Accordingly, on information and belief, an outer surface of each of the space filling compartments is configured to align against greater and lesser curvatures of the gastric cavity.

155. Claim 15 of the '930 patent generally recites the method of claim 12, wherein at least partly filling the plurality of isolated chambers comprises (i) releasably attaching an inflation tube to the valve system and (ii) introducing the fluid into a first isolated chamber of the plurality of isolated chambers through the inflation tube.

156. The Infringing Instrumentalities infringe claim 15 of the '930 patent. The chambers of the ReShape balloons are filled after they are positioned in the patient's stomach. ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, pp. 16-17, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). The instructions state: "Connect the inflation tubing to the proximal balloon fill tube (catheter lanyard

1) and inflate to the desired volume. Monitor inflation under endoscopic visualization.” *Id.* at 17. “The ReShape™ Valve Sealant is necessary to seal the device valves and prevent balloon leakage.” *Id.* at 17. Accordingly, on information and belief, the ReShape balloons are filled by releasibly attaching an inflation tube to the valve system and introducing the fluid into a first chamber of the inflatable space-filling chambers through the inflation tube.

157. Claim 16 of the ‘930 patent generally recites the method of claim 12, wherein introducing the gastric balloon structure to the gastric cavity comprises introducing the gastric balloon structure through an esophagus of the patient.

158. The Infringing Instrumentalities infringe claim 16 of the ‘930 patent. ReShape Dual Balloons are delivered through endoscopic procedures and “insertion and removal may be completed in an endoscopy suite.” See <http://pro.reshapeready.com/about-reshape/#theadvantages>.

159. Claim 17 of the ‘930 patent generally recites the method of claim 12, wherein a diameter of the gastric balloon structure is no larger than 2 centimeters prior to inflation.

160. Upon information and belief, the Infringing Instrumentalities infringe claim 17 of the ‘930 patent. See ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, pp. 2, 16-17, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf).

161. Claim 18 of the ‘930 patent generally recites the method of claim 12, wherein fluid in each of the plurality of isolated chambers is a same type of fluid.

162. The Infringing Instrumentalities infringe claim 18 of the ‘930 patent. The ReShape dual balloons are both filled with saline and remain at a fixed volume until they are removed. See <https://www.youtube.com/watch?v=U91FsjtMf3o>; [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf), Sec. 2.1 – 2.7 at p. 15-16.

163. Claim 19 of the ‘930 patent recites “a system for treating obesity, comprising: a means for conforming a flexible, space-filling structure to a natural kidney shape of a gastric cavity of a patient . . . .” The Infringing Instrumentalities infringe claim 19 of the ‘930 patent. The ReShape Dual Balloon “is a temporary implant designed to facilitate weight loss by

occupying space in the stomach.” ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, p. 1, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). The figure below, taken from ReShape’s instruction manual, shows the dual balloon in a patient’s stomach.

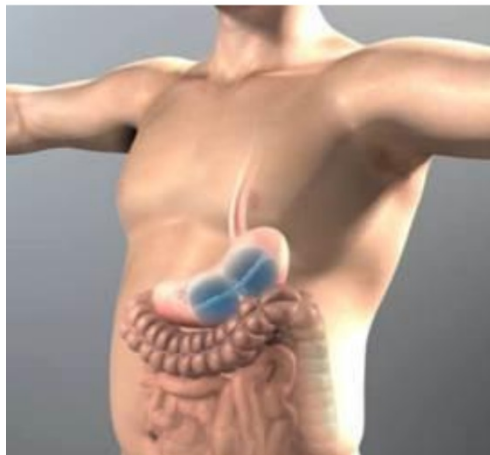


Figure 1. *ReShape* Dual Balloon in the Stomach

The ReShape Dual Balloon mimics “the natural curvature of the stomach, the dual gastric balloon is designed to conform to the patient’s anatomy and enhance tolerability.” See <http://pro.reshapeready.com/about-reshape/#theadvantages>.

164. Claim 19 of the ‘930 patent further recites “a means for maintaining at least two isolated inflatable regions of the flexible, space-filling structure such that a collective volume of the at least two isolated inflatable regions remaining inflated after deflation of any single isolated inflatable region of the at least two isolated inflatable regions prevents the flexible, space-filling structure from passing through the pylorus of the patient . . . .” Figure 1 of the Instructions for Use shows that the ReShape balloon has two nonconcentric and adjacent chambers. The introduction of the fluid to the balloons is described at pages 16-17 of the Instructions for Use, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). The ReShape website states that “[i]n the unlikely event of individual gastric balloon leakage or deflation, the independently sealed *ReShape* weight loss balloons are designed to minimize risk of migration or obstruction.” <http://pro.reshapeready.com/about-reshape/#theadvantages>. In

other words, the dual balloon design will prevent the implant from passing to the patient's intestinal tract in the event one of the balloons ruptures.

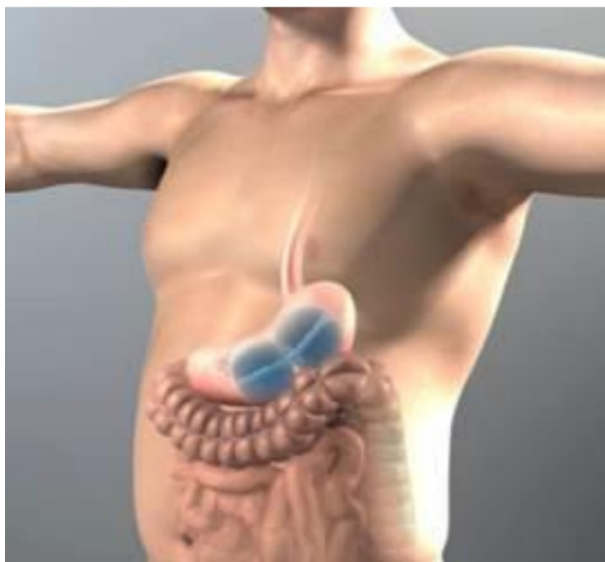
165. Claim 19 of the '930 patent further recites "a means for introducing a fluid into each of the at least two isolated inflatable regions after positioning the flexible, space-filling structure within the gastric cavity, wherein the means for introducing is configured to be separated from said means for conforming after introducing the fluid . . . ." The chambers of the ReShape balloons are filled after they are positioned in the patient's stomach. ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, pp. 16-17, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). "The ReShape™ Valve Sealant is necessary to seal the device valves and prevent balloon leakage." *Id.* at 17.

166. Lastly, claim 19 of the '930 patent recites "a means for receiving the fluid into each region of the at least two isolated inflatable regions and for retaining the fluid in each region, wherein the fluid is received from the means for introducing the fluid." The chambers of the ReShape balloons are filled after they are positioned in the patient's stomach. ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, pp. 16-17, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). "The ReShape™ Valve Sealant is necessary to seal the device valves and prevent balloon leakage." *Id.* at 17.

167. Claim 21 of the '930 patent generally recites the system of claim 19, wherein the means for conforming provides for modulated passage of food through the gastric cavity.

168. The Infringing Instrumentalities infringe claim 21 of the '930 patent. The ReShape Dual Balloon "is a temporary implant designed to facilitate weight loss by occupying space in the stomach." ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, p. 1, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). The figure below, taken from ReShape's instruction manual, shows the dual balloon in a patient's stomach providing modulated passage of food through the gastric cavity.





**Figure 1. ReShape Dual Balloon in the Stomach**

169. Claim 22 of the ‘930 patent generally recites the system of claim 19, wherein the means for conforming is configured such that, upon inflation, the flexible space-filling structure rests within the gastric cavity without exerting pressure at any point in the gastric cavity sufficient to cause ulceration.

170. The Infringing Instrumentalities infringe claim 22 of the ‘930 patent. The ReShape Dual Balloon mimics “the natural curvature of the stomach, the dual gastric balloon is designed to conform to the patient’s anatomy and enhance tolerability.” *See* <http://pro.reshapeready.com/about-reshape/#theadvantages>. Accordingly, on information and belief, it is configured to rest within the gastric cavity without exerting pressure at any point in the gastric cavity sufficient to cause ulceration.

171. Claim 23 of the ‘930 patent generally recites the system of claim 22, wherein undue pressure against the gastric cavity is avoided in part through at least one of i) a fill weight of collective volumes of the at least two isolated inflatable regions, ii) a distribution of the overall space-filling structure, and iii) a buoyancy of the fluid.

172. The Infringing Instrumentalities infringe claim 23 of the ‘930 patent. The ReShape Balloon prevents undue pressure through a fill weight of collective volumes of the at least two isolated inflatable regions. ReShape’s instructions for use state as follows:



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.

See [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)

at 16. ReShape instructs the user to determine the size of the patient and to select a corresponding fill volume for the balloon structure. Further, the ReShape Dual Balloon prevents undue pressure through a distribution of the overall space-filling structure in that it mimics “the natural curvature of the stomach, the dual gastric balloon is designed to conform to the patient’s anatomy and enhance tolerability.” See <http://pro.reshapeready.com/about-reshape/#theadvantages>.

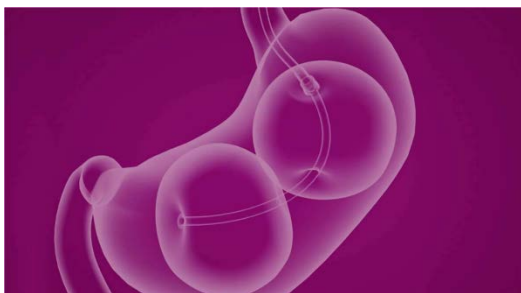
173. Claim 24 of the ‘930 patent generally recites the system of claim 19, wherein the means for receiving the fluid comprises a respective valve structure of each region of the at least two isolated inflatable regions, the respective valve structure comprising at least a first valve and a second valve.

174. Upon information and belief, the Infringing Instrumentalities infringe claim 24 of the ‘930 patent. The chambers of the ReShape balloons are filled after they are positioned in the patient’s stomach. ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, pp. 16-17, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). Each of the two balloons in the ReShape Balloon are filled through a valve system as demonstrated by the instructional videos and instruction manual, which states “[t]he ReShape™ Valve Sealant is necessary to seal the device valves and prevent balloon leakage.” *Id.*; see also <https://www.youtube.com/watch?v=U91FsjtMf3o>; <http://pro.reshapeready.com/about-reshape/> (providing an in-patient medical instructional video about placement, inflation, and removal of the ReShape Balloon). Accordingly, on information and belief, the ReShape Balloon valves comprise a respective valve structure of each region of the at least two isolated inflatable regions, the respective valve structure comprising at least a first valve and a second valve.

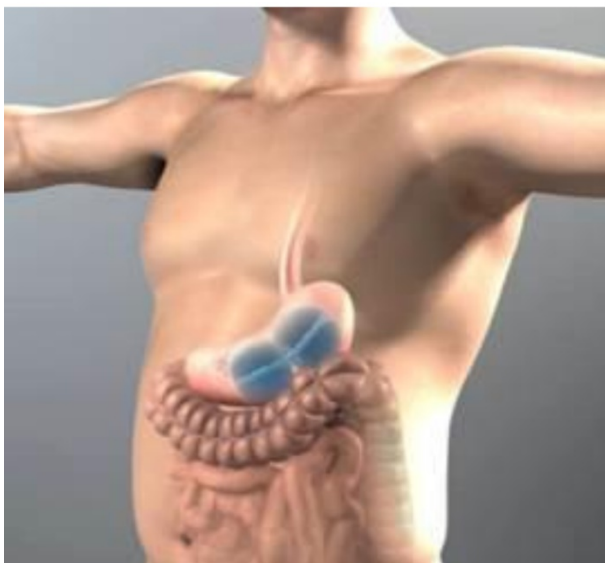
175. Claim 25 of the ‘930 patent generally recites the system of claim 19, further comprising a means for flexibly connecting at least a first region of the at least two isolated

inflatable regions and a second region of the at least two isolated inflatable regions by spanning a gap between the first region and the second region, thereby forming a cavity between the first region and the second region through which food may pass.

176. The Infringing Instrumentalities infringe claim 25 of the '930 patent. The flexible central spine element is illustrated in the video provided on ReShape's website, a frame from which is reproduced below. See <https://reshapeready.com/reshape-cc/>; see also <https://www.youtube.com/watch?v=U91FsjtMf3o>.



The conformance of the dual balloon to the stomach of the patient is shown in the image above and is also illustrated in Figure 1 of ReShape's instructions for use, reproduced below.



**Figure 1. ReShape Dual Balloon in the Stomach**

Accordingly, on information and belief, the ReShape Balloon's spine flexibly connects at least a first region of the at least two isolated inflatable regions and a second region of the at least

two isolated inflatable regions by spanning a gap between the first region and the second region, thereby forming a cavity between the first region and the second region through which food may pass.

177. Claim 26 of the '930 patent generally recites the system of claim 25, wherein the means for flexibly connecting at least the first isolated inflatable region and the second isolated inflatable region is in fluid communication with the means for receiving the fluid.

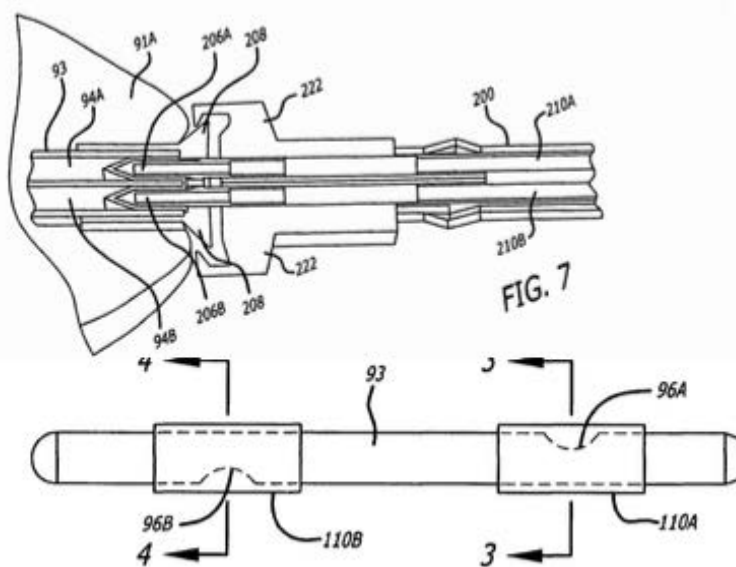
178. Upon information and belief, the Infringing Instrumentalities infringe claim 26 of the '930 patent. The flexible central spine element is illustrated in the video provided on ReShape's website, a frame from which is reproduced below. *See*

<https://reshapeready.com/reshape-cc>; *see also*

<https://www.youtube.com/watch?v=U91FsjtMf3o>.



Further, ReShape's patent, U.S. 8,142,469, shows that the inflation lumens and valves are carried by the flexible central spine as shown below:



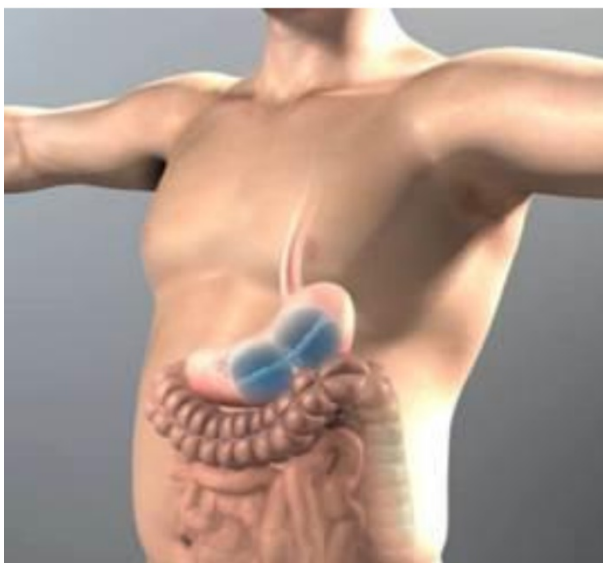
Accordingly, on information and belief, the ReShape Balloon's spine is in fluid communication with the means for receiving the fluid.

179. Claim 27 of the '930 patent generally recites the system of claim 25, wherein the means for flexibly connecting comprises a flexible central spine.

180. The Infringing Instrumentalities infringe claim 27 of the '930 patent. The flexible central spine element is illustrated in the video provided on ReShape's website, a frame from which is reproduced below. See <https://reshapeready.com/reshape-cc/>; see also <https://www.youtube.com/watch?v=U91FsjtMf3o>.



The conformance of the dual balloon to the stomach of the patient is shown in the image above and is also illustrated in Figure 1 of ReShape's instructions for use, reproduced below.



**Figure 1. *ReShape* Dual Balloon in the Stomach**

181. Claim 30 of the '930 patent generally recites the system of claim 19, wherein fluid in each of the at least two isolated inflatable regions is a same type of fluid.

182. The Infringing Instrumentalities infringe claim 30 of the '930 patent. The ReShape dual balloons are both filled with saline and remain at a fixed volume until they are removed. See <https://www.youtube.com/watch?v=U91FsjtMf3o>; [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf), Sec. 2.1 – 2.7 at p. 15-16.

183. On information and belief, the Infringing Instrumentalities are used marketed, provided to, and/or used by or for the Infringing ReShape Entities' partners, clients, customers and end users across the country and in this District.

184. On information and belief, SV Health, through its control, of the Infringing ReShape Entities has been aware of the existence of the '930 patent since its issuance.

185. On information and belief, since at least the time SV Health, through its control, of the Infringing ReShape Entities has been aware of the '930 patent, it has induced and continues to induce others to infringe at least one claim of the '930 patent under 35 U.S.C. § 271(b) by, among other things, and with specific intent or willful blindness, actively aiding and abetting others to infringe, including but not limited to the Infringing ReShape Entities to infringe at least one claim of the '930 patent.

186. SV Health's infringement of the '930 patent has been, and continues to be knowing, intentional, and willful, in whole or in part because SV Health, through its control of the Infringing ReShape Entities has been aware of the '930 patent since its issuance and continue to engage in infringing conduct. SV Health, through its control of the Infringing ReShape Entities had knowledge of all major aspects of Fulfillium's business plans, including trade secrets divulged pursuant to an oral agreement of confidentiality. SV Health through its control of the Infringing ReShape Entities knew that Fulfillium was actively engaged in patenting its gastric balloon technology. Further, SV Health through its control of the Infringing ReShape Entities. was fully aware that the Infringing ReShape entities technology would copy many aspects of Dr. Chen's inventions because it was developed after and with knowledge of Dr. Chen's designs. The fact that ReShape Medical, Inc. knew of Dr. Chen's patents and believed those patents to be relevant to ReShape Medical, Inc.'s gastric balloon technology is demonstrated by ReShape Medical, Inc.'s citation of Dr. Chen's patents as relevant prior art when attempting to procure its own patents. For instance, in December 2012 ReShape Medical, Inc. filed an information disclosure statement with the United States Patent and Trademark Office indicating that Dr. Chen's previous patent applications were relevant to ReShape Medical, Inc.'s pending patent application directed to the ReShape Balloon. Upon information and belief SV Health actively directed or could have directed ReShape Medical, Inc. to file patent applications covering its gastric balloon technology.

187. Each of SV Health's acts of infringement of the '930 patent have caused and will continue to cause Fulfillium damages for which Fulfillium is entitled to compensation pursuant to 35 U.S.C. § 284.

188. Each of SV Health's acts of infringement of the '930 patent have caused and will continue to cause Fulfillium immediate and irreparable harm unless such infringing activities are enjoined by this Court pursuant to 35 U.S.C. § 283. Fulfillium has no adequate remedy at law.

189. This case is exceptional and, therefore, Fulfillium is entitled to an award of attorneys' fees pursuant to 35 U.S.C. § 285.

**COUNT III – INFRINGEMENT OF U.S. PATENT NO. 9,808,367**

190. Fulfillium repeats the allegations of paragraphs 1-189 above as though fully set forth herein.

191. On November 7, 2017, U.S. Patent No. 9,808,367 (“the ‘367 patent”), entitled “Methods, Devices, and Systems for Obesity Treatment,” was duly and legally issued by the United States Patent and Trademark Office. A true and correct copy of the ‘367 patent is attached as Exhibit 4.

192. Fulfillium is the assignee and owner of the right, title and interest in and to the ‘367 patent, including the right to assert all causes of action arising under said patents and the right to any remedies for infringement of them by at least an assignment dated July 17 2018. Ex. A.

193. On information and belief, the Infringing ReShape Entities make, use, sell, offer to sell, and/or import medical devices. A description of ReShape Lifesciences’ business is available on its business website, which is located at <http://pro.reshapeready.com>; <https://reshapeready.com/>.

194. As part of its business, the Infringing ReShape Entities make, use, offer to sell, sell, and/or import a dual intragastric balloon for weight loss, including ReShape Medical’s “Duo Balloon” device, which is placed inside the patient’s stomach for weight loss. Infringing ReShape Entities have purposefully sold and offered for sale such Duo Balloon devices throughout the United States.

195. Upon information and belief, the Infringing ReShape Entities have and continue to directly infringe at least claims 1-2, 4-7, 11-12, and 16-21 of the ‘367 patent by making, using, selling, importing and/or providing and causing to be used medical devices for weight loss, including but not limited to, those sold under the name ReShape Duo Balloon (the “Infringing Instrumentalities”).

196. Upon information and belief, SV Health has and continues to indirectly infringe at least claims 1-2, 4-7, 11-12 and 16-21 of the ‘367 patent by, among other things, and with specific intent or willful blindness, actively aiding and abetting the Infringing ReShape Entities

to directly infringe at least claims 1-2, 4-7, 11-12, and 16-21 of the ‘367 patent by the Infringing ReShape Entities sale of the Infringing Instrumentalities.

197. Representative claim 1 of the ‘367 patent recites a “free floating, untethered gastric balloon structure for deploying in a gastric cavity of a patient, comprising: at least two isolated non-concentric inflatable chambers, wherein each chamber of the at least two isolated non-concentric inflatable chambers has a respective inflated state volume such that deflation of any single chamber of the at least two isolated non-concentric inflatable chambers leaves the inflated state volume of the remaining chambers of the at least two isolated non-concentric inflatable chambers unaffected[.]” The Infringing Instrumentalities infringe claim 1 of the ‘367 patent. The ReShape Dual Balloon “is a temporary implant designed to facilitate weight loss by occupying space in the stomach.” ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, p. 1, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf); *see also* <https://reshapeready.com/reshape-cc/>. The figures below, taken from ReShape’s instruction manual and documentation, show the dual balloon untethered in a patient’s stomach. The ReShape website states that “[i]n the unlikely event of individual gastric balloon leakage or deflation, the independently sealed *ReShape* weight loss balloons are designed to minimize risk of migration or obstruction.” <http://pro.reshapeready.com/about-reshape/#theadvantages>. In other words, each balloon inflates and deflates independently. *See also* <https://www.youtube.com/watch?v=U91FsjtMf3o>.





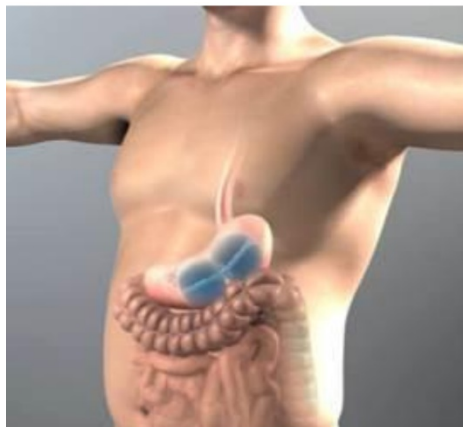
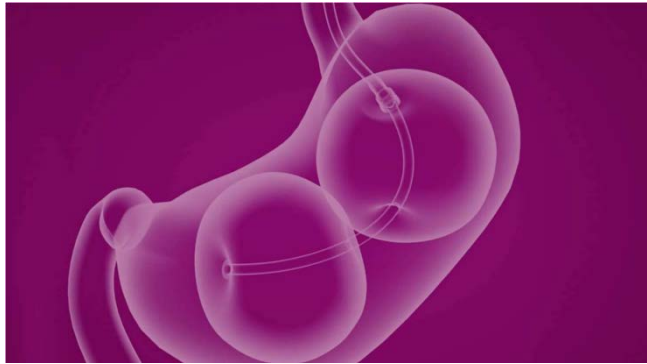


Figure 1. *ReShape* Dual Balloon in the Stomach

198. Claim 1 of the ‘367 patent further recites “a valve system for introducing a fluid into the at least two isolated non-concentric inflatable chambers and for retaining, upon inflation, the fluid in the at least two isolated non-concentric inflatable chambers.” The chambers of the *ReShape* balloons are filled after they are positioned in the patient’s stomach. *ReShape*™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, pp. 16-17, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). “The *ReShape*™ Valve Sealant is necessary to seal the device valves and prevent balloon leakage.” *Id.*; see also <https://www.youtube.com/watch?v=U91FsjtMf3o>; U.S. Pat. No. 8,142,469 at Fig. 1, 3-5.

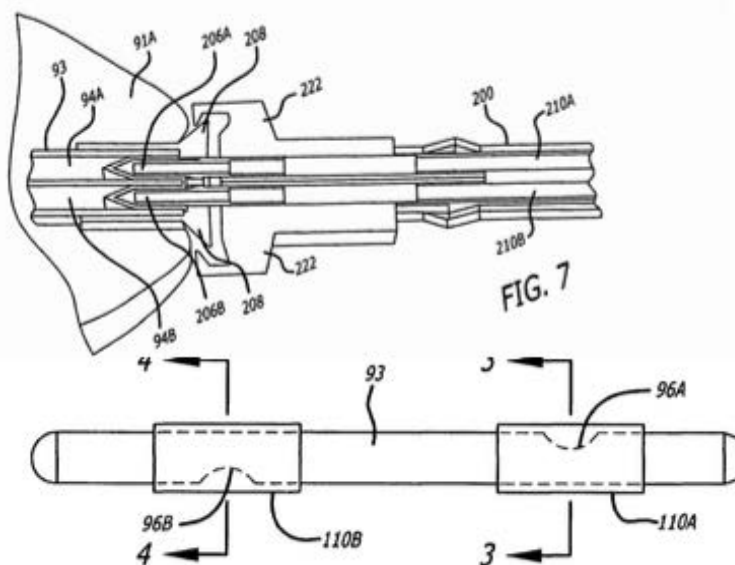
199. Claim 1 further recites “a flexible member spanning a gap between and fixedly attached to both a first chamber of the at least two isolated non-concentric inflatable chambers and a second chamber of the at least two isolated non-concentric inflatable chambers, said flexible member carrying inflation tubes that are in fluid communication with the at least two isolated non-concentric inflatable chambers; wherein the gastric balloon structure is configured to float freely in the patient’s gastric cavity and is not connected to any catheter, lumen or tether after deployment in the patient’s gastric cavity[.]” The flexible member element is illustrated in the video provided on *ReShape*’s website, a frame from which is reproduced below. See <https://reshapeready.com/reshape-cc/>; see also <https://www.youtube.com/watch?v=U91FsjtMf3o>.



Upon information and belief, the flexible member of the dual balloon carries inflation tubes that are in fluid communication with the two isolated non-concentric inflatable chambers. The flexible member element is illustrated in the video provided on ReShape's website, a frame from which is reproduced below. *See* <https://reshapeready.com/reshape-cc> ;/ *see also* <https://www.youtube.com/watch?v=U91FsjtMf3o> .



Further, ReShape's patent, U.S. 8,142,469, shows that the inflation lumens and valves are carried by the flexible member as shown below:



Accordingly, on information and belief, the ReShape balloon's flexible member is in fluid communication with the means for distributing the fluid. The following images below from ReShape's website and instruction manual demonstrate that a tether is not used in the ReShape Balloon System. *See generally* <https://reshapeready.com/reshape-cc/>; ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, p. 1, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf).



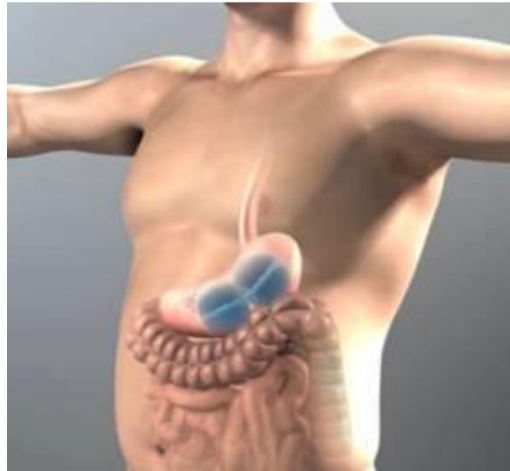


Figure 1. *ReShape* Dual Balloon in the Stomach

200. The final recitation in claim 1 recites “wherein the gastric balloon structure, in its inflated state, assumes a curved shape conforming to a natural three dimensional kidney shape of the gastric cavity, such that the flexible member flexibly conforms, upon at least partially filling the at least two isolated non-concentric inflatable chambers, the gastric balloon structure to the natural three-dimensional kidney shape of the gastric cavity.” The conformance of the dual balloon to the stomach of the patient is shown in the image above and is also illustrated in Figure 1 of ReShape’s instructions for use, reproduced below.



Figure 1. *ReShape* Dual Balloon in the Stomach

201. Claim 2 of '367 patent generally recites the gastric balloon structure of claim 1, wherein the gastric balloon structure is configured to provide for modulated passage of food through the gastric cavity upon inflation.

202. The Infringing Instrumentalities infringe claim 2 of the '367 patent. The ReShape Dual Balloon "is a temporary implant designed to facilitate weight loss by occupying space in the stomach." ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, p. 1, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). The figure below, taken from ReShape's instruction manual, shows the dual balloon in a patient's stomach providing modulated passage of food through the gastric cavity upon inflation.

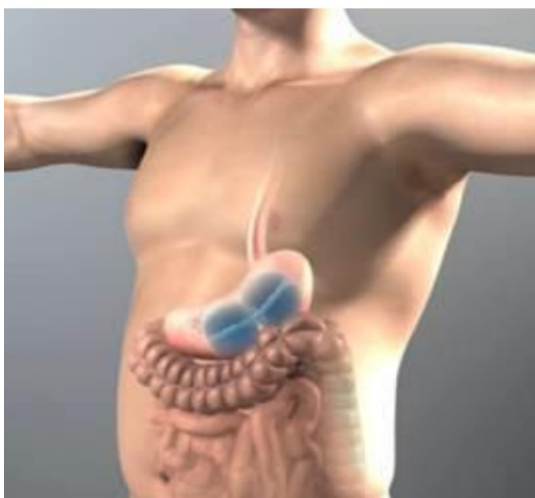


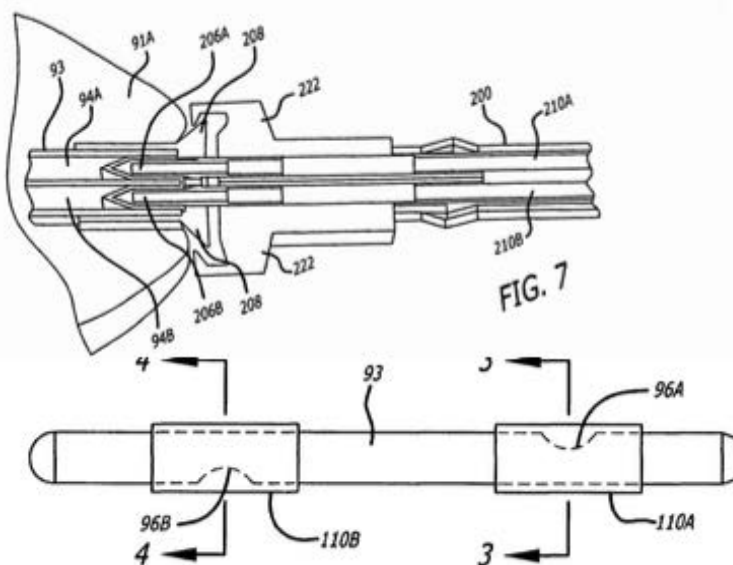
Figure 1. *ReShape* Dual Balloon in the Stomach

203. Claim 4 of the '367 patent generally recites the gastric balloon structure of claim 1, wherein the flexible member is in fluid communication with the valve system.

204. Upon information and belief, the Infringing Instrumentalities infringe claim 4 of the '367 patent. The flexible member element is illustrated in the video provided on ReShape's website, a frame from which is reproduced below. See <https://reshapeready.com/reshape-cc/>; see also <https://www.youtube.com/watch?v=U91FsjtMf3o>.



Further, ReShape's patent, U.S. 8,142,469, shows that the inflation lumens and valves are carried by the flexible member as shown below:



Accordingly, on information and belief, the ReShape Balloon's flexible member is in fluid communication with the valve system.

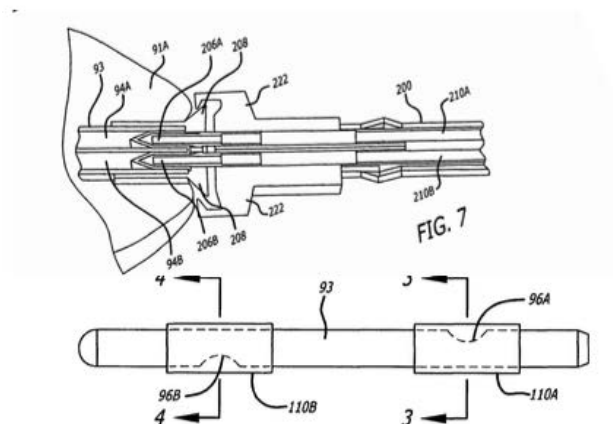
205. Claim 5 of the '367 patent generally recites the gastric balloon structure of claim 4, wherein the flexible member encloses an inflation lumen for introducing the fluid into the at least two isolated non-concentric inflatable chambers.

206. Upon information and belief, the Infringing Instrumentalities infringe claim 5 of the '367 patent. The chambers of the ReShape balloons are filled after they are positioned in the

patient's stomach. ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, pp. 16-17, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). “The ReShape™ Valve Sealant is necessary to seal the device valves and prevent balloon leakage.” *Id.*; *see also* <https://www.youtube.com/watch?v=U91FsjtMf3o>. The flexible member element is illustrated in the video provided on ReShape's website, a frame from which is reproduced below. *See* <https://reshapeready.com/reshape-cc/>.



Further, ReShape's patent, U.S. 8,142,469, shows that the inflation lumens and valves are carried by the flexible member as shown below:



Accordingly, on information and belief, the ReShape Balloon's flexible member encloses an inflation lumen for introducing the fluid into the at least two isolated non-concentric inflatable chambers.

207. Claim 6 of the ‘367 patent generally recites the gastric balloon structure of claim 1, wherein the gastric balloon structure is configured to maintain the inflated state volume of each of the at least two isolated non-concentric inflatable chambers while deployed in the gastric cavity of the patient without controlled adjustment.

208. The Infringing Instrumentalities infringe claim 6 of the ‘367 patent. The ReShape dual balloons are both filled with saline and remain at a generally fixed volume until they are removed. See <https://www.youtube.com/watch?v=U91FsjtMf3o>; [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf), Sec. 2.1 – 2.7 at p. 15-16, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf).

209. Claim 7 of the ‘367 patent generally recites the gastric balloon structure of claim 1, wherein each chamber of the at least two isolated non-concentric inflatable chambers is filled with a same fluid.

210. The Infringing Instrumentalities infringe claim 7 of the ‘367 patent. The ReShape dual balloons are both filled with saline and remain at a fixed volume until they are removed. See <https://www.youtube.com/watch?v=U91FsjtMf3o>; [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf), Sec. 2.1 – 2.7 at p. 15-16.

211. Claim 11 of the ‘367 patent generally recites the gastric balloon structure of claim 1, wherein, upon inflation, the gastric balloon structure is configured to rest within the gastric cavity without exerting pressure at any point in the gastric cavity sufficient to cause abrasion, pressure induced lesions, or other trauma.

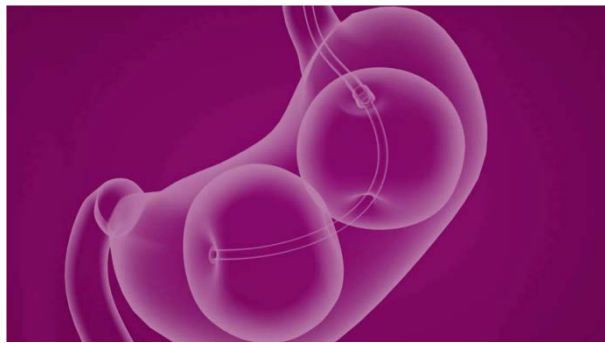
212. The Infringing Instrumentalities infringe claim 11 of the ‘367 patent. The ReShape Dual Balloon mimics “the natural curvature of the stomach, the dual gastric balloon is designed to conform to the patient’s anatomy and enhance tolerability.” See <http://pro.reshapeready.com/about-reshape/#theadvantages>. Accordingly, on information and belief, it is configured to rest within the gastric cavity without exerting pressure at any point in the gastric cavity sufficient to cause abrasion, pressure induced lesions, or other trauma.



213. Claim 12 of the '367 patent generally recites the gastric balloon structure of claim 11, wherein an outer surface of each of the isolated non-concentric inflatable chambers is configured to align against greater and lesser curvatures of the gastric cavity.

214. The Infringing Instrumentalities infringe claim 12 of the '367 patent. The ReShape Dual Balloon mimics “the natural curvature of the stomach, the dual gastric balloon is designed to conform to the patient’s anatomy and enhance tolerability.” See

<http://pro.reshapeready.com/about-reshape/#theadvantages>.



The conformance of the dual balloon to the stomach of the patient is shown in the image above and is also illustrated in Figure 1 of ReShape’s instructions for use, reproduced below.

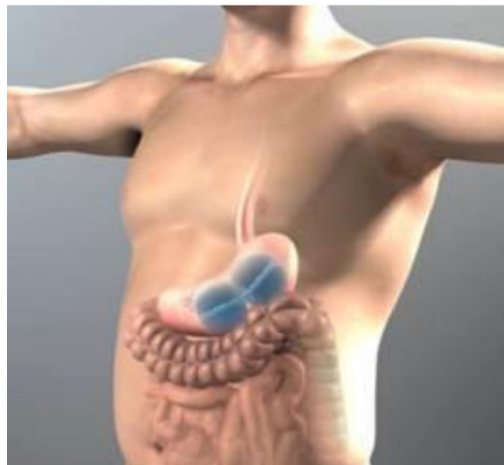
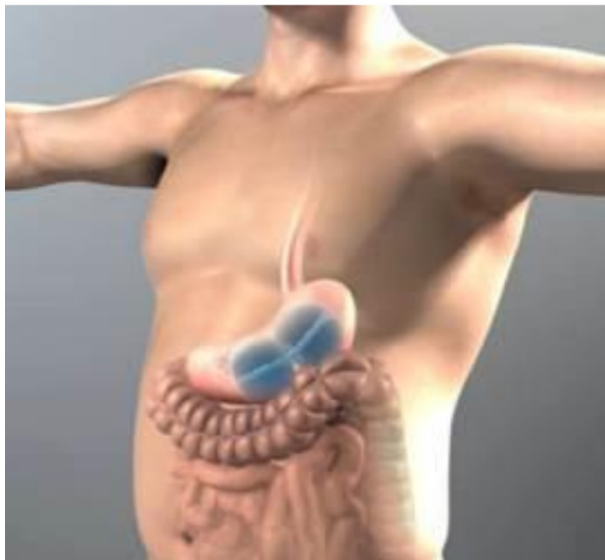


Figure 1. *ReShape* Dual Balloon in the Stomach

Accordingly, on information and belief, an outer surface of each of the isolated non-concentric inflatable chambers is configured to align against greater and lesser curvatures of the gastric cavity.

215. Claim 16 of the ‘367 patent generally recites “An obesity treatment system for deployment in a stomach of a patient such that the system is free-floating and untethered after deployment, comprising: a plurality of adjacent, non-concentric, spaced apart inflatable space-filling compartments, wherein each compartment of the plurality of inflatable space-filling compartments has a respective inflated state volume during treatment of the patient[.]” The Infringing Instrumentalities infringe claim 16 of the ‘367 patent. The ReShape Dual Balloon “is a temporary implant designed to facilitate weight loss by occupying space in the stomach.” ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, p. 1, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf); *see also* <https://reshapeready.com/reshape-cc/>. The figures below, taken from ReShape’s instruction manual and documentation, show the dual balloon untethered in a patient’s stomach. The ReShape website states that “[i]n the unlikely event of individual gastric balloon leakage or deflation, the independently sealed *ReShape* weight loss balloons are designed to minimize risk of migration or obstruction.” <http://pro.reshapeready.com/about-reshape/#theadvantages>. In other words, each balloon inflates and deflates independently and its inflated volume is maintained. *See also* <https://www.youtube.com/watch?v=U91FsjtMf3o>.



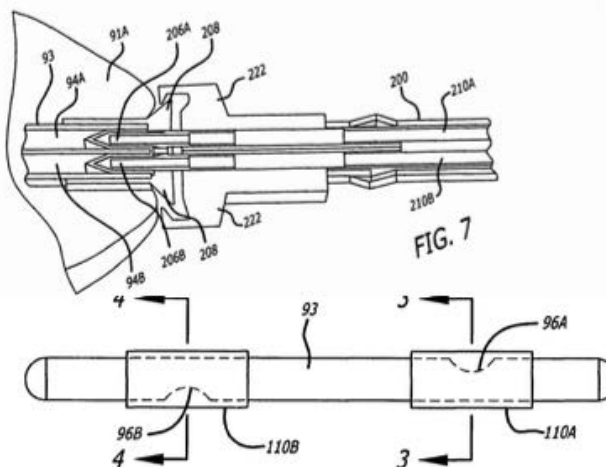


**Figure 1. ReShape Dual Balloon in the Stomach**

216. Claim 16 of the ‘367 patent further recites “at least two valves to introduce at least one fluid into each of the plurality of inflatable space-filling compartments and to retain, after inflation, fluid in the plurality of inflatable space-filling compartments[.]” The chambers of the ReShape balloons are filled after they are positioned in the patient’s stomach. ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, pp. 16-17, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). “The ReShape™ Valve Sealant is necessary to seal the device valves and prevent balloon leakage.” *Id.*; see also <https://www.youtube.com/watch?v=U91FsjtMf3o>; U.S. Pat. No. 8,142,469 at Fig. 1, 3-5.

217. Claim 16 of the ‘367 patent further recites “wherein each valve is a one-way valve and wherein at least one of the at least two valves has a proximal end configured to removably attach to an inflation tube[.]” The chambers of the ReShape balloons are filled after they are positioned in the patient’s stomach. ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, pp. 16-17, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). The instructions state: “Connect the inflation tubing to the proximal balloon fill tube (catheter lanyard 1) and inflate to the desired volume. Monitor inflation under endoscopic visualization.” *Id.* at 17. “The ReShape™ Valve Sealant is necessary to seal the device valves and prevent balloon leakage.” *Id.*; see also

<https://www.youtube.com/watch?v=U91FsjtMf3o>; Further, ReShape's patent, U.S. 8,142,469, shows a one-way valves as shown below at 206A and 96A:



Accordingly, on information and belief, each valve of the ReShape Balloon is a one-way valve and at least one of the at least two valves has a proximal end configured to removably attach to an inflation tube.

218. Claim 16 of the '367 patent further recites "wherein the plurality of inflatable space-filling compartments form, upon at least partially filling the plurality of inflatable space-filling compartments, a dual balloon system that is configured to float within the stomach; wherein the dual-balloon system is configured to float freely in the patient's stomach and is not connected to any catheter, lumen or tether after deployment in the patient's stomach[.]" The video on ReShape's website shows how the dual balloon structure floats within the stomach without use of a catheter, lumen or other tether. <https://reshapeready.com/reshape-cc/>. A frame from that video is reproduced below.



The ability of the dual balloon to float within the stomach of the patient without a tether is also illustrated in Figure 1 of ReShape’s instructions for use, reproduced below.

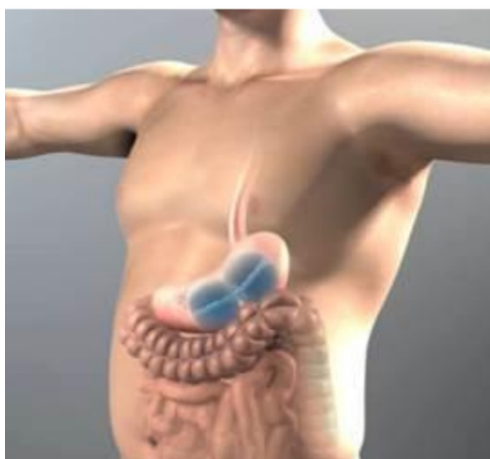


Figure 1. *ReShape* Dual Balloon in the Stomach

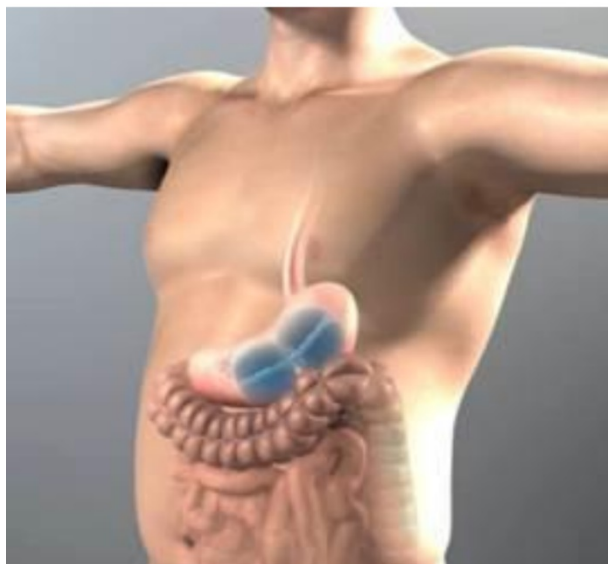
219. Lastly, claim 16 of the ‘367 patent recites “wherein, upon inflation, the dual balloon system is configured to float within the stomach without exerting pressure at any point in the stomach sufficient to cause abrasion, pressure induced lesions, or other trauma.” The ReShape Dual Balloon mimics “the natural curvature of the stomach, the dual gastric balloon is designed to conform to the patient’s anatomy and enhance tolerability.” See <http://pro.reshapeready.com/about-reshape/#theadvantages>. Accordingly, on information and belief, it is configured to rest within the gastric cavity without exerting pressure at any point in the gastric cavity sufficient to cause abrasion, pressure induced lesions, or other trauma.

220. Claim 17 of the '367 patent generally recites the obesity treatment system of claim 16, wherein an outer surface of each of the inflatable space-filling compartments abuts a greater or lesser curvature of the stomach.

221. The Infringing Instrumentalities infringe claim 17 of the '367 patent. The ReShape Dual Balloon mimics “the natural curvature of the stomach, the dual gastric balloon is designed to conform to the patient’s anatomy and enhance tolerability.” See <http://pro.reshapeready.com/about-reshape/#theadvantages>.



The conformance of the dual balloon to the stomach of the patient is shown in the image above and is also illustrated in Figure 1 of ReShape’s instructions for use, reproduced below.

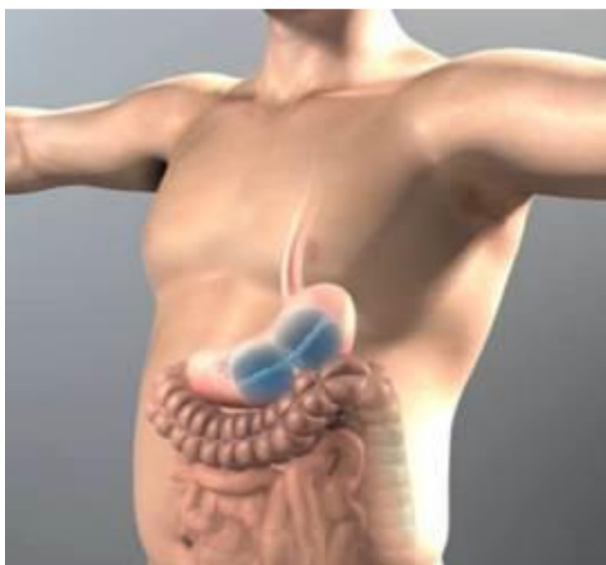


**Figure 1. *ReShape* Dual Balloon in the Stomach**

Accordingly, on information and belief, an outer surface of each of the inflatable space filling compartments abuts a greater or lesser curvature of the stomach.

222. Claim 18 of the '367 patent generally recites the obesity treatment system of claim 16, wherein the plurality of inflatable space-filling compartments are untethered in the stomach after inflation.

223. The Infringing Instrumentalities infringe claim 18 of the '367 patent. The following images below from ReShape's website and instruction manual demonstrate that the ReShape Balloon is untethered in the stomach after inflation. *See generally* <https://reshapeready.com/reshape-cc/>; ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, p. 1, [https://reshapeready.com/wp-content/uploads/2015/07/ReShape\\_Instructions\\_For\\_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf).

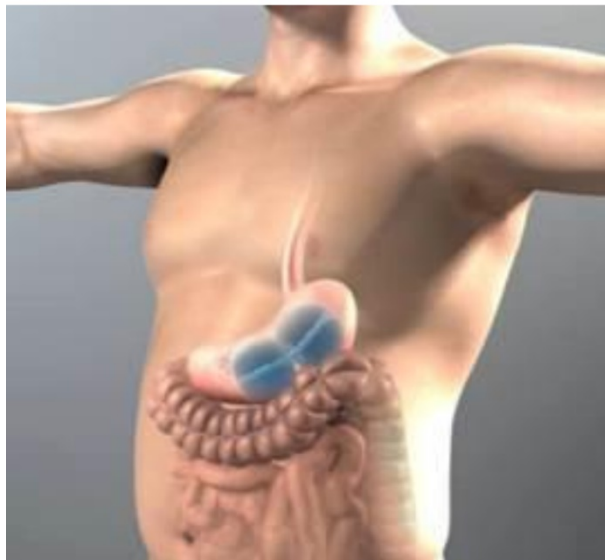


**Figure 1. ReShape Dual Balloon in the Stomach**



224. Claim 19 of the '367 patent generally recites the obesity treatment system of claim 16, further comprising a flexible central spine structure spanning a gap between and connecting the plurality of adjacent, spaced apart inflatable space-filling compartments.

225. The Infringing Instrumentalities infringe claim 19 of the '367 patent. The flexible central spine element is illustrated in the video provided on ReShape's website, a frame from which is reproduced below. See <https://reshapeready.com/reshape-cc/>; see also <https://www.youtube.com/watch?v=U91FsjtMf3o>.



**Figure 1. ReShape Dual Balloon in the Stomach**

Accordingly, on information and belief, the ReShape Balloon's flexible central spine structure spans a gap between and connects the plurality of adjacent, spaced apart inflatable space-filling compartments.

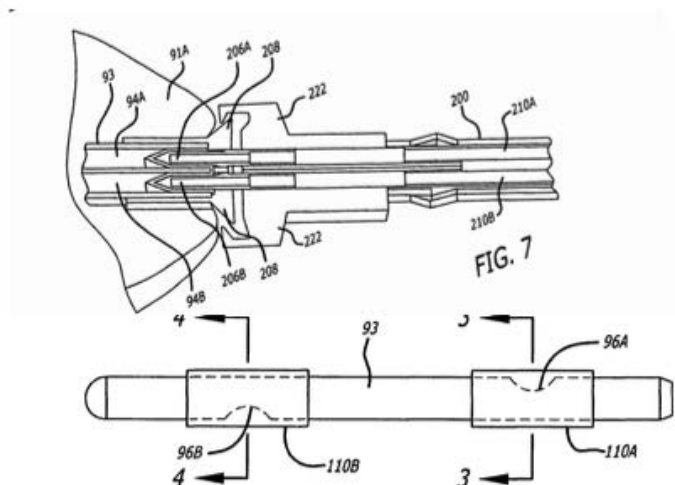


226. Claim 20 of the '367 patent generally recites the obesity treatment system of claim 19, wherein the flexible central spine structure is in fluid communication with the valve system.

227. Upon information and belief, the Infringing Instrumentalities infringe claim 20 of the '367 patent. The flexible central spine element is illustrated in the video provided on ReShape's website, a frame from which is reproduced below. *See* <https://reshapeready.com/reshape-cc/>; *see also* <https://www.youtube.com/watch?v=U91FsjtMf3o>.



Further, ReShape's patent, U.S. 8,142,469, shows that the inflation lumens and valves are carried by the flexible central spine as shown below:



Accordingly, on information and belief, the ReShape Balloon's flexible central spine structure is in fluid communication with the valve system.

228. Claim 21 of the '367 patent generally recites the obesity treatment system of claim 20, wherein the flexible central spine structure encloses an inflation lumen for introducing the fluid into the plurality of inflatable space-filling compartments.

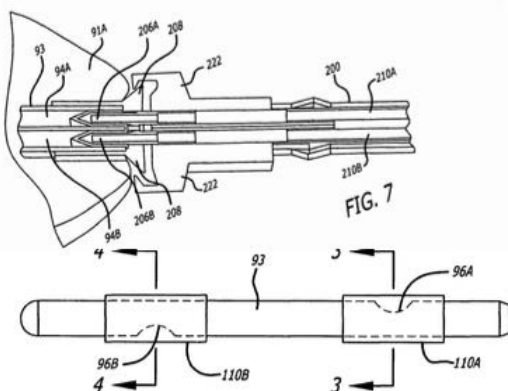
229. Upon information and belief, the Infringing Instrumentalities infringe claim 21 of the '367 patent. The flexible central spine element is illustrated in the video provided on ReShape's website, a frame from which is reproduced below. *See*

<https://reshapeready.com/reshape-cc/>; *see also*

<https://www.youtube.com/watch?v=U91FsjtMf3o>.



Further, ReShape's patent, U.S. 8,142,469, shows that the inflation lumens and valves are carried by the flexible central spine as shown below:



Accordingly, on information and belief, the ReShape Balloon's flexible central spine structure encloses an inflation lumen for introducing the fluid into the plurality of inflatable space-filling compartments.

230. On information and belief, the Infringing Instrumentalities are used marketed, provided to, and/or used by or for the Infringing ReShape Entities' partners, clients, customers and end users across the country and in this District.

231. On information and belief, SV Health through its control of the Infringing ReShape Entities has been aware of the existence of the '367 patent since its issuance.

232. On information and belief, since at least the time SV Health through its control of the Infringing ReShape Entities has been aware of the '367 patent, it has induced and continues to induce others to infringe at least one claim of the '367 patent under 35 U.S.C. § 271(b) by, among other things, and with specific intent or willful blindness, actively aiding and abetting others to infringe, including but not limited to the Infringing ReShape Entities to infringe at least one claim of the '367 patent.

233. SV Health's infringement of the '367 patent has been, and continues to be knowing, intentional, and willful, in whole or in part because SV Health through its control of the Infringing ReShape Entities has been aware of the '367 patent since its issuance and continues to engage in infringing conduct. SV Health through its control of the Infringing ReShape entities had knowledge of all major aspects of Fulfillium's business plans, including trade secrets divulged pursuant to an oral agreement of confidentiality. SV Health through its control of the Infringing ReShape Entities knew that Fulfillium was actively engaged in patenting its gastric balloon technology. Further, SV Health through its control of the Infringing ReShape Entities was fully aware that the Infringing ReShape Entities technology would copy many aspects of Dr. Chen's inventions because it was developed after and with knowledge of Dr. Chen's designs. The fact that ReShape Medical, Inc. knew of Dr. Chen's patents and believed those patents to be relevant to ReShape Medical, Inc.'s gastric balloon technology is demonstrated by ReShape Medical, Inc.'s citation of Dr. Chen's patents as relevant prior art when attempting to procure its own patents. For instance, in December 2012 ReShape Medical, Inc. filed an information disclosure statement with the United States Patent and Trademark Office indicating that Dr. Chen's previous patent applications were relevant to ReShape Medical, Inc.'s pending patent application directed to the ReShape Balloon. Additionally, Fulfillium sent

ReShape Medical, Inc. (and consequently ReShape Medical LLC and ReShape Lifesciences) received explicit notice of the '367 patent via letter on November 14, 2017. Upon information and belief, SV Health was aware of this through its control of the Infringing ReShape Entities.

234. Each of SV Health's acts of infringement of the '367 patent have caused and will continue to cause Fulfillium damages for which Fulfillium is entitled to compensation pursuant to 35 U.S.C. § 284.

235. Each of ReShape Medical LLC and ReShape Lifesciences' acts of infringement of the '367 patent have caused and will continue to cause Fulfillium immediate and irreparable harm unless such infringing activities are enjoined by this Court pursuant to 35 U.S.C. § 283. Fulfillium has no adequate remedy at law.

236. This case is exceptional and, therefore, Fulfillium is entitled to an award of attorneys' fees pursuant to 35 U.S.C. § 285.

#### **JURY DEMAND**

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff demands a trial by jury on all issues triable as such.

#### **PRAYER FOR RELIEF**

WHEREFORE, Fulfillium respectfully requests that the Court enter judgment against Defendants as follows:

A. An adjudication that SV Health has infringed the '915, '930, and '367 patents in violation of 35 U.S.C. § 271;

B. A granting of an injunction permanently enjoining SV Health its employees, agents, officers, directors, attorneys, successors, affiliates, subsidiaries and assigns, and all of those in active concert and participation with any of the foregoing persons or entities from infringing, contributing to the infringement of, or inducing infringement of the '915, '930, and '367 patents;

C. An order to SV Health to account and pay damages adequate to compensate Fulfillium for SV Health's infringement of the '915, '930, and '367 patents, with pre-judgment

and post-judgment interest and costs, pursuant to 35 U.S.C. § 284, and an accounting of all infringing acts not presented at trial;

D. An order that the damages award be increased up to three times the actual amount assessed, pursuant to 35 U.S.C. § 284;

E. A declaration that this case is exceptional under 35 U.S.C. § 285, and an award of Fulfillium's reasonable costs and fees, including attorneys' fees, with interest; and

F. An award to Fulfillium of such other and further relief as this Court deems just and proper.

Dated: August 24, 2018

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