Spatz3 Adjustable Balloon System

Physician's Instructions for Use

Spatz FGIA, Inc.

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
Rx Only

Contents

1. INTRODUCTION

Prior to undergoing the placement of the Spatz3 Adjustable Balloon, patients must be evaluated individually by the physician and the bariatric support team. Physicians are required to review with each patient the risks and benefits of the treatment and to determine the appropriateness for the individual patient. Physicians must meet the following requirements prior to becoming a Spatz3 Adjustable Balloon Center:

- Upper endoscopy training at a certified residency or fellowship with endoscopy privileges granted by a hospital or ambulatory facility.
- Completion of a Spatz training program.
- Have a comprehensive therapeutic weight management support program that includes nutrition and exercise counselling.

A comprehensive medical history and physical examination is performed by the physician to determine a patient's suitability for the procedure and to ensure the patient is not contraindicated for device use. Immediately prior to balloon implantation an EGD (esophagogastroduodenoscopy) is performed to rule out any contraindicating pathology as listed in the contraindication section.

Please see the last page for directions on obtaining additional information.

2. INFORMATION THAT SHOULD BE PROVIDED TO THE PATIENT

Spatz3 Adjustable Balloon placement is an elective procedure, and the patient must be well counselled on the risk-benefit relationship. The physician must inform the patient of the warnings, precautions, and adverse events listed in this package insert and provide the patient with a copy of the Patient Information Booklet. The physician should also advise the patient that early removal of the balloon may be required due to intolerance or due to serious adverse events. Balloon volume adjustments require another endoscopy procedure with sedation, which can help many patients avoid early extraction or enhance weight loss results; however, it may not help every patient.

Physicians should be aware and should impart to their patients that the success of the Spatz3 Adjustable Balloon treatment is dependent on clinic support and patient cooperation. The clinic support should include a dietician/nutritionist who will guide the patient through the different phases of the treatment – visits at least monthly with phone or digital communication in-between visits are necessary to ensure patient safety. This support guides patients in choices and quantities of food ingestion as well as understanding symptoms from the balloon. This needs to be coordinated with the medical follow-up by the doctor or clinical assistant under the supervision of the doctor. The patient needs to cooperate and communicate with the clinic staff and return for frequent visits and most importantly, communicate any change in symptoms promptly.

3. DEVICE DESCRIPTION

The Spatz3 Adjustable Balloon System is designed to assist weight loss by partially filling the stomach and delaying gastric emptying.

Figure 1. Spatz3 Adjustable Balloon in the folded pre-insertion state (left) and fully inflated (right)

The Spatz3 Adjustable Balloon System® is provided in a sealed envelope, which contains the following elements: the Spatz3 Adjustable Balloon, the cap (in its own sealed envelope), the insertion facilitator (in its own sealed envelope) and the extension tube with 3-way stopcock on its proximal end. The Spatz3 Adjustable Balloon is placed in the stomach and filled with saline, causing it to expand into a spherical shape. The filled balloon is designed to act as a space filler and move freely within the stomach.

The maximum placement period for the **Spatz3 Adjustable Balloon** is 8 months, and it must be removed at that time or earlier.

The unique inflation tube design of the **Spatz3 Adjustable Balloon** permits balloon volume adjustment at the time of placement and at a later time. Balloon volume may range from 300 - 850 ml (400-550 ml starting volume, and after adjustments may range from 300 - 850 ml).

4. INDICATIONS FOR USE

The Spatz3 Adjustable Balloon System is indicated for temporary use for weight loss in adults with obesity Body Mass Index (BMI) of 35.0-40.0 kg/m^2 or a BMI of 30.0 to 34.9 kg/m^2 with one or more major obesity-related comorbid conditions who have failed to achieve and maintain weight-loss with a supervised weight control program. The Spatz3 Adjustable Balloon System is to be used in conjunction with a long-term supervised diet and behavior modification program designed to increase the possibility of long-term weight-loss maintenance. The maximum placement period for Spatz3 Adjustable Balloon System is 8 months.

5. CONTRAINDICATIONS

- Prior gastrointestinal surgery with sequelae, i.e., recurrent abdominal pain, bowel obstruction, episodes of transient bowel obstruction, adhesive peritonitis or known abdominal adhesions; prior intestinal resection; or prior multiple lower abdominal or pelvic surgeries.
- Prior open or laparoscopic bariatric surgery.
- Prior surgery of any kind on the esophagus, stomach, duodenum or any type of hiatal hernia surgery.
- Any inflammatory disease of the gastrointestinal tract including esophagitis, Barrett's esophagus, gastric ulceration, duodenal ulceration, or specific inflammation such as Crohn's disease, or cancer or other diseases of the bowel system.
- Potential upper gastrointestinal bleeding conditions such as esophageal or gastric varices, congenital or acquired intestinal telangiectasis, or other congenital anomalies of the gastrointestinal tract such as atresias or stenoses.
- A gastric mass.
- A hiatal hernia > 2cm or severe or intractable gastro-esophageal reflux symptoms.
- Acid reflux symptoms to any degree that require more than one medication for symptom control.
- A structural abnormality in the esophagus or pharynx such as a stricture or diverticulum that could impede passage of the balloon alongside the endoscope.
- Achalasia or any other severe esophageal motility disorder that may pose a safety risk during the removal of the device
- Severe coagulopathy.
- Insulin-dependent diabetes (either Type 1 or Type 2) or a significant likelihood of requiring insulin treatment in the following 12 months.
- Subjects with any serious health condition unrelated to their weight that would increase the risk of endoscopy
- Chronic abdominal pain
- Motility disorders of the gastrointestinal tract such as gross esophageal motility disorders, gastroparesis or intractable constipation
- Hepatic insufficiency or cirrhosis
- Serious or uncontrolled psychiatric illness or disorder that could compromise patient understanding of or compliance with follow up visits and removal of the device after 8 months.
- Alcoholism or drug addiction.
- Patients receiving daily prescribed treatment with aspirin > 100 mg, anti-inflammatory agents, anticoagulants or other gastric irritants.

- Patients who are unable or unwilling to take prescribed proton pump inhibitor medication for the duration of the device implant.
- Patients who are known to have, or suspected to have, an allergic reaction to materials contained in the system.
- Patients who have BOTH -ever developed a serotonin syndrome AND are currently taking any drug known to affect the levels of serotonin in the body [e.g., selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), monoamine oxidase inhibitors (MAOIs)] should not undergo placement of the device.
- Patients who are pregnant or breast-feeding.
- Patients with Severe cardiopulmonary disease or other serious organic disease, which might include known history of coronary artery disease, myocardial infarction within the past 6 months, poorly controlled hypertension, required use of NSAIDs
- Patients who are currently positive for H. Pylori.
- Patients taking medications on specified hourly intervals that may be affected by changes to gastric emptying, such as anti-seizure or anti-arrhythmic medications
- Patients who are taking corticosteroids, immunosuppressants, or narcotics
- Symptomatic congestive heart failure, cardiac arrhythmia or unstable coronary artery disease.
- Pre-existing respiratory disease such as chronic obstructive pulmonary disease (COPD) or pneumonia.
- Pre-existing cancer undergoing chemotherapy or radiation therapy.
- Diagnosis of autoimmune connective tissue disorder (e.g., lupus, erythematous, scleroderma) or immunocompromised.
- Life expectancy less than 1 year or severe renal, hepatic, pulmonary or cardiac condition.
- Specifically diagnosed genetic or hormonal cause for obesity such as Prader Willi syndrome or untreated hypothyroidism
- Eating disorders including night eating syndrome (NES), bulimia, binge eating disorder, or compulsive overeating
- Untreated endocrine disorders affecting weight
- The presence of more than one intragastric balloon at the same time

6. WARNINGS

- Intestinal obstructions have been reported due to deflated balloons passing into the intestines and have required surgical removal. Death due to intestinal obstruction is possible and has been reported with intragastric balloons. Patients experiencing any symptoms of an intestinal obstruction (e.g., acute onset of abdominal pain, nausea or vomiting) should be counselled to seek immediate care.
- The maximum placement period for the Spatz3 Adjustable Balloon is 8 months. The risk of intragastric balloon deflation and intestinal obstruction (and therefore possible emergency surgical intervention and death), ulceration and gastric perforation is significantly higher when balloons are left in place longer than 8 months.
- Patients who have had prior abdominal surgery with sequelae i.e., obstruction, and/or adhesive peritonitis or known abdominal adhesions are contraindicated for balloon insertion. It is therefore imperative to discern whether patients with a history of abdominal surgery have had sequelae or not.
- The presence of blue-green urine or sudden loss of satiety, increased hunger and/or weight gain may be a sign of balloon deflation. Patients should be instructed to immediately contact their physician if they observe any of these signs. Clinical means of assessing possible deflation include abdominal x-ray, ultrasound, barium swallow, CAT Scan and endoscopy. In some cases, the balloon can be vomited or passed in the bowel movement. If the deflated balloon passes into the intestine, it could result in intestinal obstruction requiring surgery. If the balloon is vomited, patients can experience laryngospasm, hypoxia, esophageal injury, and pulmonary aspiration.
- Patients may not observe or report the presence of blue-green urine following a balloon deflation. Patients should be counselled to seek immediate care if any symptoms of an intestinal obstruction such as acute abdominal pain, nausea or vomiting develop.
- Deflated balloons must be removed promptly. The risk of intestinal obstruction (and therefore possible emergency surgical intervention and death) is significantly higher when deflated devices are not removed promptly.
- Failure of patients to take prescribed daily proton-pump inhibitor medication increases the risk of gastric ulceration or perforation.
- Using direct endoscopic visualization, confirm proper positioning of the uninflated balloon in the stomach prior to inflation. Failure to do so may cause injury to the esophagus, pylorus or duodenum.
- Patients receiving serotonergic drugs including SSRIs, SNRIs, MAOIs and other prescription and over-the-counter drugs (such as dextromethorphan, which is commonly used in cough/cold medications; St.John’s wort, which is used for depression) should be cautioned about the possibility of developing serotonin syndrome because of the combination of these medications and the release of methylene blue (in the event of balloon rupture). Patients should immediately seek medical attention if they develop any symptoms of confusion, headache, nausea and vomiting, rapid heart rate, or severe sweating. Serotonin syndrome has been reported in patients given serotonergic

psychiatric medications and methylene blue via intravenous administration of methylene blue at doses ranging from 1 mg/kg to 8 mg/kg.

- In the event of balloon rupture, methylene blue would be released into the stomach and absorbed into the circulation. Methylene blue is a drug with multiple pharmacological indications. Methylene blue is a DNA binding agent that tests positive for mutagenicity and DNA damage in bacteria, yeast, mammalian cells, and human tissue obtained after clinical exposures. The internal release of methylene blue would result in a local concentration that is higher than that delivered by the usual IV injection route. The consequences of transient acute methylene blue exposure following balloon rupture are not known.
- Patients should immediately notify their doctor if they become pregnant while the device is in place, as there is a risk for release of methylene blue and birth defects (in the event of balloon rupture). An association exists between the use of methylene blue in amniocentesis and birth defects.
- The catheter (tubing) external to the balloon can enter into the duodenum. Usually the symptoms are short lived, however, there have been cases of nausea, vomiting, pain, acid reflux and dehydration requiring endoscopy to reposition the balloon, downsize the balloon or remove the balloon.
- Balloons can develop surface colonization known as Biofilm. For example, the rate in Brazil is 14.9% of intragastric balloons. In the US Pivotal study, 1/187 Spatz3 Adjustable Balloons deflated with the presence of surface biofilm. While biofilm colonization of the balloon surface usually is without sequelae, it can negatively affect the balloon integrity leading to balloon deflation and rarely, bowel obstruction requiring surgery.
- Prior to balloon adjustment or balloon extraction procedures, a 72-hour liquid diet and 12-hour period with nothing by mouth (NPO) is required prior to the procedure. The balloon causes gastroparesis, which will allow food retention in the stomach – therefore, a standard NPO post-midnight preparation is not sufficient. Failure to follow these dietary and fasting guidelines will raise the risk of aspiration during the procedure. Note: In the event of intractable nausea/vomiting, a preparatory diet cannot be undertaken and an emergency procedure should be done – endotracheal intubation should be considered to prevent aspiration.
- Acute pancreatitis has been reported due to intragastric balloon use. Patients with complaints of abdominal pain, nausea and vomiting, which are suggestive of pancreatitis, should be evaluated with serum amylase or lipase. Patients with pancreatitis should be followed closely and may require balloon extraction and hospitalization.
- Spontaneous Hyperinflation can occur in fluid-filled intragastric balloons. It is characterized by the spontaneous hyperinflation of the balloon with air causing an enlargement of the balloon, which can lead to abdominal pain, nausea and vomiting, and in severe cases it can lead to ulceration, and rarely it can cause gastric perforation and death. Any change in symptoms – new onset nausea, vomiting, pain, or trouble breathing

– needs to be addressed by the physician to rule out among other things, spontaneous hyperinflation. If a balloon is found to be hyperinflated, it should be removed.

7. PRECAUTIONS

- It is the responsibility of the physician to advise the patient of known risks and complications associated with the procedure and the device.
- It is the responsibility of the physician to advise the patient of the potential need to remove the device in less than 8 months due to balloon deflation. In the event of gastrointestinal intolerance, the physician may advise the patient to decrease balloon volume.
- It is the responsibility of the physician to advise the patient that the maximum placement period for the Spatz3 Adjustable Balloon is 8 months and it must be removed at that time or earlier.
- Patients must be counselled on the need for proper dietary and exercise habits. Failure to adhere to prescribed dietary and exercise instructions may result in failure to lose weight.
- Insertion and removal of the Spatz3 Adjustable Balloon should only be performed by physicians experienced in diagnostic and therapeutic endoscopy procedures.
- Each patient must be monitored closely during the entire term of treatment to detect the development of possible complications. Each patient should be instructed regarding signs and symptoms of balloon deflation, gastrointestinal obstruction, perforation, ulceration and other complications, which might occur, and should be advised to contact his/her physician immediately upon the onset of such signs and symptoms.
- Any change in symptoms – new onset nausea, vomiting, pain, or trouble breathing – needs to be addressed by the doctor. The cause may include dietary indiscretion, ulceration, hyperinflation, perforation or obstruction. In certain circumstances the doctor will choose to do an x-ray, or endoscopy, if dietary/medication changes do not alleviate symptoms. Prompt attention is recommended to prevent serious complications.
- It is recommended that all patients be tested for H. pylori and, if found to have a positive test, be treated in accordance with the standard of care prior to Spatz3 Adjustable Balloon insertion.
- Ensure that the patient has followed the recommended pre-procedure diet instructions so that no food or liquid is present in the stomach at the time of the insertion procedure, adjustment, or extraction procedures.
- In the event of an emergency removal, endotracheal intubation of the patient should be considered to reduce the risk of aspiration.
- Subjects who are found at retrieval endoscopy to have a gastric ulcer should be placed on 6 – 8 weeks of therapeutic proton pump inhibitor (PPI) medication and followed closely. After completing 6 – 8 weeks of PPI treatment, subjects experiencing potential ulcer symptoms or signs such as abdominal pain or discomfort, dyspepsia, anemia or dark stools should be considered for endoscopic examination to assess ulcer resolution.
- Inflation volumes above 850 ml are not recommended and may increase risk of intolerance, balloon deflation, gastric ulceration and/or gastric perforation.

- The Spatz3 Adjustable Balloon is composed of soft silicone elastomer and is easily damaged by instruments, sharp objects or fingernails. The balloon must be handled only with gloved hands as indicated in the Instructions for Use.
- The 50 ml sterile syringe is supplied in its original packaging and is meant for one-use only. Re-use of the syringe can result in fluid contamination and balloon hyperinflation. Use of a syringe less than 50 ml is not recommended as it will increase the risk of damage to the inflation tube and valve.
- Patients reporting loss of satiety, increased hunger and/ or weight gain should be evaluated by physical exam and in some cases examined radiographically and/or endoscopically, as this may be indicative of a balloon deflation. Should the loss of satiety, increased hunger and/or weight gain not be associated with balloon deflation or other physiological cause, and the balloon is below the recommended maximum (850 ml) capacity, the physician may consider increasing the balloon volume.
- If it is necessary to replace a balloon, which has spontaneously deflated, the recommended initial fill volume of the replacement balloon is the same as for the first balloon or the most recent volume of the removed balloon, unless the patient is considered clinically ready for a balloon volume increase. A greater initial fill volume in the replacement balloon may result in severe nausea, vomiting or ulcer formation
- It is important to discuss all possible complications and adverse events with the patient. Complications that may result from use of this product include those associated with general endoscopy procedures, those associated with the Spatz3 Adjustable Balloon specifically and those associated with the patient's degree of intolerance to an implanted foreign body.
- The physiological response of the patient to the presence of the Spatz3 Adjustable Balloon may vary depending upon the patient's general condition and the level and type of activity. The types and frequency of administration of drugs or diet supplements and the overall diet of the patient may also affect the response.

8. POTENTIAL ADVERSE EVENTS

The complications described below may be severe enough to require adjustment of balloon volume or early removal of the Spatz3 Adjustable Balloon. The risks of intestinal obstruction, ulceration, and perforation are increased if the device is implanted for greater than 8 months. If intestinal migration occurs, the device may pass through the intestine and be passed with stool. However, surgical, therapeutic radiologic or endoscopic removal may be required. Death due to intestinal obstruction and perforation is possible and has been reported with intragastric balloons. Surgery could result in a colostomy, ileostomy, chest tube and other unforeseen procedures. Any of these complications can be mild to severe, short or long lasting for months, and can result in the need for oral or IV medications, IV hydration, absence from work or inability to work for short or extended periods. After balloon removal, the recuperation period can last for days to weeks, but depending on underlying condition could take longer.

It is important to discuss all possible complications and adverse events with your patient. Complications that may result from the use of this product include the risks associated with the medications and methods utilized in the endoscopic procedure, the risks associated with any endoscopic procedure, the risks associated with the Spatz3 Adjustable Balloon specifically, and the risks associated with the patient's degree of intolerance to a foreign object placed in the stomach.

8.1 Possible Adverse Events

Complications associated with the use of the Spatz3 Adjustable Balloon are detailed in Sections 8.2 and 8.3 below, and include:

- Gastric outlet obstruction. A partially-filled balloon or a leaking balloon could lead to gastric outlet obstruction, requiring balloon removal. It is also possible for a fully inflated balloon to lodge itself in the gastric outlet causing a pyloric obstruction, which can produce a mechanical impediment to gastric emptying. Gastric outlet obstruction may require surgical removal.
- Bacterial growth in the fluid, which fills the balloon. Rapid release of this fluid into the intestine could cause infection, fever, cramps and diarrhea.
- Gastric atony resulting in gastric food accumulation, which can lead to rotting of food which, becomes infected with spillage into the intestines and diarrhea – a bacterial overgrowth type situation
- Balloon deflation and subsequent replacement.
- Intestinal obstruction by the balloon. An insufficiently filled balloon or a leaking balloon that has lost sufficient volume may be able to pass from the stomach into the small bowel. It may pass all the way into the colon and be passed with stool. However, if there is a narrow area in the bowel, as may occur after prior surgery on the bowel or adhesion formation, the balloon may not pass and then may cause a bowel obstruction. If this occurs, surgery or endoscopic removal could be required.
- Esophageal obstruction. Once the balloon is being filled in the stomach, the balloon could be inadvertently pulled back into the esophagus. If this occurs, surgery or endoscopic removal could be required.

- Gastric distention with retained food and fluid due to severely delayed gastric emptying with or without outlet obstruction from displacement of the balloon into the antrum.
- Injury to the digestive tract during placement of the balloon in an improper location such as in the esophagus or duodenum. This could cause bleeding and perforation, which could require a surgical or endoscopic correction for control.
- Insufficient or no weight loss.
- Adverse health consequences resulting from weight loss such as gallstones, dehydration, loss of muscle mass, mood changes, electrolyte abnormalities, menstrual changes and nutritional deficiencies.
- Gastric discomfort, feelings of nausea and vomiting following balloon placement as the digestive system adjusts to the presence of the balloon.
- Continuing nausea and vomiting. This could result from direct irritation of the lining of the stomach, delayed gastric emptying and/or the balloon blocking the outlet of the stomach. It is even theoretically possible that the balloon could prevent vomiting (not nausea or retching) by blocking the inlet to the stomach from the esophagus.
- A feeling of heaviness in the abdomen.
- Abdominal or back pain, either steady or cyclic.
- Gastroesophageal reflux.
- Injury to the lining of the digestive tract as a result of direct contact with the endoscope, the balloon, grasping forceps or as a result of increased acid production by the stomach. This could lead to ulcer formation with pain, bleeding or even perforation. Surgery could be necessary to correct this condition.
- Death due to adverse events related to intestinal obstruction, gastroesophageal perforation, and/or pulmonary aspiration is possible
- Acute pancreatitis characterized by nausea, vomiting, abdominal pain, dehydration. The severity can range from mild to severe and may require balloon down adjustment, or removal. This may result in hospitalization, surgery or death in severe cases.
- Spontaneous hyperinflation due to gas production within the balloon. Spontaneous hyperinflation can cause abdominal pain, nausea and vomiting, and in severe cases it can lead to ulceration, and rarely it can cause gastric perforation and death.

Potential risks associated with upper endoscopic procedures include but are not limited to: abdominal cramping and discomfort from the air used to distend the stomach, sore or irritated throat, bleeding, infection, tearing of the esophagus or stomach, and aspiration pneumonia. Some of these risks may lead to death. The risk increases if additional procedures are performed. According to the American College of Gastroenterology, risks related to sedation during endoscopic procedures are rare, occurring in less than one in every 10,000 people[11]. The most common complications involve a temporary decrease in the rate of breathing or heart rate, which can be corrected by giving extra oxygen or by reversing the effect of the sedative medications.

[1] Vargo J. (Jul 2005, Nov 2008). "American College of Gastroenterology." Retrieved July 16, 2015 from http://patients.gi.org/topics/sedation-for-endoscopy/

Patients with heart, lung, kidney, liver, or other chronic diseases are at higher risk for complications. Drug dosages and airway management should be taken into consideration when treating high-risk patients.

8.2 Complications observed in the US Clinical Study

For full information and results of the complications associated with the use of the Spatz3 Adjustable Balloon noted in the US clinical study please refer to section 11.1.

8.3 Complications observed in global experience

The Spatz3 Adjustable Balloon has been approved in many countries since August 30, 2012. As of March 15, 2021, more than 76,000 devices have been distributed to countries with Spatz3 Adjustable Balloon System approval. No regulatory approvals have been revoked or withdrawn. The Spatz complaint database houses vigilance reports for adverse events submitted to various competent authorities by mandatory reporters (manufacturers, importers, and device user facilities) and voluntary reporters such as healthcare professionals, patients, and consumers. Device- and procedure-related adverse events or complaints reported through clinical product surveillance and literature reviews are contained within these data. All complaints spanning a period from August 30, 2012 to March 15, 2021 are presented in Table 1; however, these data have not been scientifically validated and may include duplication of some events due to multiple sources of data collection. Some events have not been directly attributed to the Spatz3 Adjustable Balloon. Global product use outside of the US may include a treatment course up to 1 year instead of 8 months. It has not been established to what extent the longer treatment course may contribute to the rate of events reported in Table 1.

Bond failure has been remedied with 12,614 improved devices implanted between March 2020 and March 2021.

Table 1. Spatz3 Adjustable Balloon device- and procedure- related adverse events and complaints reported through clinical product surveillance between August 30, 2012 and March 15, 2021, compared with the period between March 2020 and March 2021

	Aug 2012 to Mar 2021		**March 2020 to March 2021**	
# of balloons	**76,000**		**12,614**	
Event	**Count**	**† Rate (%)**	**Count**	**† Rate (%)**
Serious Adverse Events				
Deflation & Migration with bowel Obstructed	23	0.030	0	0.000
Ulcer	22	0.029	0	0.000
Stomach Perforation	19	0.025	1	0.008
Death*	7	0.009	0	0.000
Esophageal Perforation	3	0.004	0	0.000

Dehydration	2	0.003	0	0.000
Gastric outlet obstruction	2	0.003	0	0.000
Gastritis	1	0.001	0	0.000
Allergic Reaction	1	0.001	0	0.000
Bowel Perforation	1	0.001	0	0.000
Bleeding	1	0.001	0	0.000
Pancreatitis**	0	0.000	0	0.000
Aspiration**	0	0.000	0	0.000
Device Failures leading to inability to Implant				
Inflation tube tear	181	0.238	10	0.079
Hole in the Balloon Prior/during Implantation	28	0.037	7	0.055
Procedure usability complications***	12	0.016	2	0.016
Use errors	6	0.008	1	0.008
Valve Disconnected	3	0.004	0	0.000
Inflation tube too long	1	0.001	0	0.000
Extension tube leak	1	0.001	0	0.000
Defective valve	1	0.001	0	0.000
Device Failures leading to inability to Adjust				
Procedure usability complications	9	0.012	0	0.000
Valve Disconnected	2	0.003	0	0.000
Inflation tube knotted	2	0.003	0	0.000
Broken Funnel	1	0.001	1	0.008
Cap nylon loop tear	1	0.001	0	0.000
White catheter broke	4	0.005	0	0.000
Device Failures during treatment phase				
Balloon Deflations for all reasons	1668	2.195	38	0.301
Deflation from Balloon Bond failure****	628	0.826	2	0.016
Deflation with insufficient information to determine cause	400	0.526	10	0.079
Deflation & passage in the stool	260	0.342	3	0.024
Deflation caused by fungal infection	222	0.292	8	0.063
Deflation caused by Cap Failure	44	0.058	13	0.103
Deflation caused by Balloon microholes	37	0.049	2	0.016
Spontaneous Hyperinflation	32	0.042	2	0.016
Deflation caused by Balloon Burst	31	0.041	0	0.000
Deflation & Migration with bowel Obstructed	23	0.030	0	0.000
Deflation & balloon vomited	18	0.024	0	0.000
Deflation & Migration caused by fungal infection	5	0.007	0	0.000

* 2 of the 7 deaths underwent autopsies and the deaths could not be definitively attributed to the Spatz3 Adjustable Balloon or the related procedures.

**Reported with other intragastric balloons
*** Reported usability complications during implantation procedures include improper use of the cap, insertion facilitator, valve-hold and extension tube.
**** Bond failure has been remedied with 12,614 improved devices implanted between March 2020 and March 2021 - reporting a bond failure rate of 0.016% (2/12,614).

† The event rate represents the counts of an event divided by the number of devices distributed as of the reporting cut-off on March 15, 2021. Note that the number of devices distributed may be greater than the number of devices placed.

9. HOW SUPPLIED

Each Spatz3 Adjustable Balloon System® Insertion Kit, Cat. No. A-SP3US-03K contains an instructions for use (IFU), chart labels, patient card, a balloon, an extension tube with its 3-way stopcock and a 50 ml luer tip syringe. The white cap for closure of the inflation valve and the insertion facilitator are provided within the packaging in separate pouches. The Spatz3 Adjustable Balloon System is provided non-sterile.

An adjustment/extraction kit, Cat. No. A-SP3-015, contains 3 extension tubes with their 3-way stopcocks and 3 IFUs. A 50 ml syringe, grasping forceps and snare are not supplied - they are readily available through medical suppliers.

WARNING: A syringe below 50 ml is not recommended and can cause high pressure and damage the inflation tube.

All are supplied FOR SINGLE USE ONLY and none should be re-used or sterilized. The risk of infection, incorrect function and patient harm are possible should these devices be re-used or sterilized.

In the event that the product becomes contaminated prior to use, it should not be used but should be returned to the manufacturer.

CAUTION: DO NOT SOAK THE DEVICE IN A DISINFECTANT. The silicone elastomer may absorb some of the solution, which could subsequently leach out and cause tissue reaction.

STORE AT ROOM TEMPERATURE (60° - 86° F)

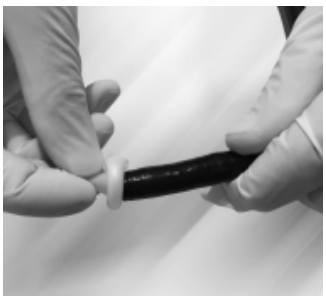
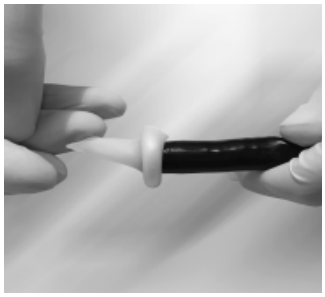
10. INSTRUCTIONS FOR USE

Use of this device requires a working knowledge of endoscopic techniques and equipment and oral-gastric intubation. The instructions for use of the Spatz3 Adjustable Balloon System do not obviate the need for formal training in these methods. The device is composed of silicone and is easily damaged if handled with tools or fingernails – only gloved hands should be used. The inflation tube is delicate - please inflate cautiously, since continued inflation while the tube is kinked can result in inflation tube tear. Use of a syringe less than 50 ml will damage the inflation system including the inflation tube and valve. The balloon should not be used if any damage is noted. A standby Spatz3 Adjustable Balloon System should be available at the time of placement. *Ensure that the patient has fasted from midnight prior to the implantation procedure.*

10.1 Insertion Instructions

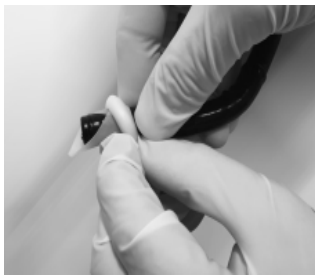
1. Conscious sedation as per standard endoscopy.
2. Perform endoscopy and assess for findings that contraindicate device implantation.
3. Remove the endoscope and dry the distal 10 cm thoroughly.
4. Remove the Spatz3 Adjustable Balloon System from the package.
5. Pull the “band-off” to remove ALL of the bands.


6. For the next steps, follow the series of photos.

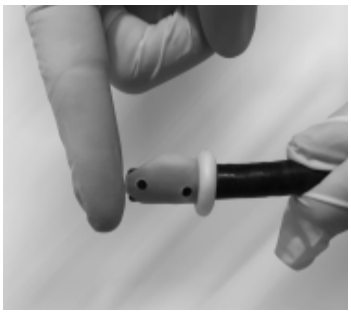



6.1 Place insertion facilitator on distal tip of scope

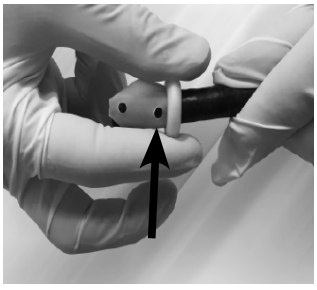
6.2 Grasp firmly and pull proximally without unrolling

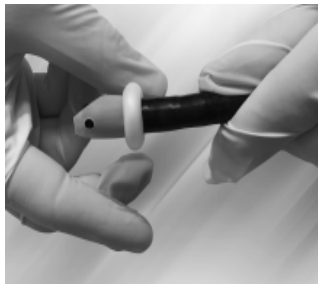


6.3 Pull the other side



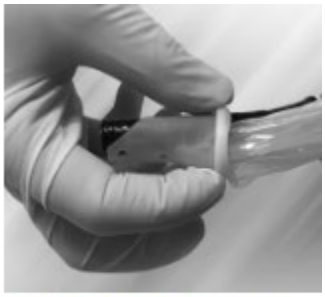
6.4 Until edge is at the tip of scope





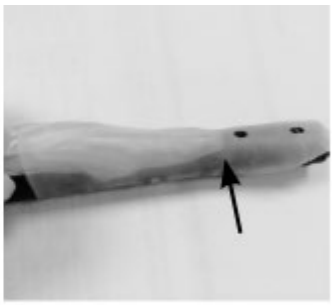
6.5 Roll back to cover proximal hole (edge may go beyond scope tip)

6.6 Place the balloon along the left side of the scope. Balloon tip touches insertion facilitator – begin unrolling

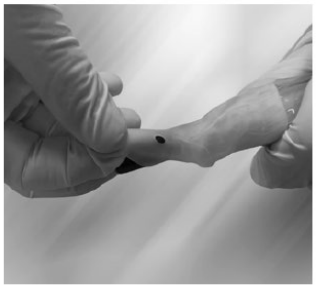


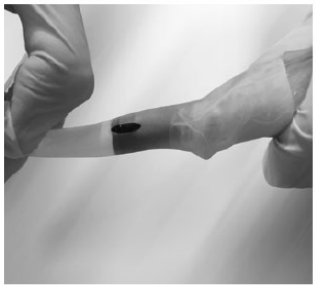
6.7 Unfold facilitator over the balloon

6.8 Complete unfolding the facilitator over the balloon

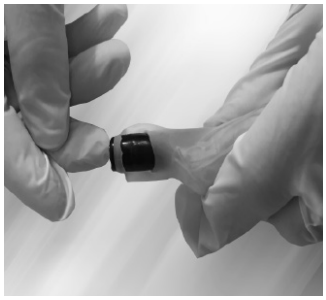


6.9 Balloon tip must be within 3-5 mm of proximal hole

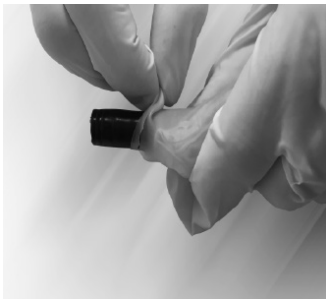




6.10. Pull the distal edge of the insertion facilitator until the proximal hole stretches over the edge of the scope. Pass the scope tip through the hole



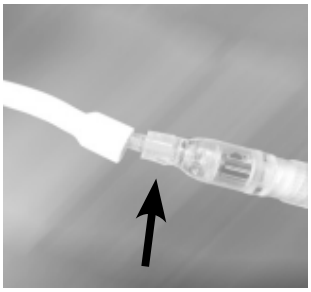
6.11 Do the same for the distal hole



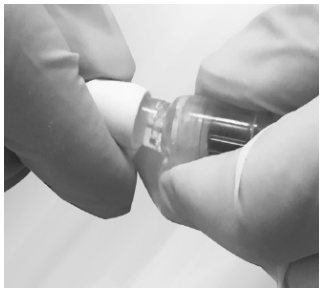
6.12 Pull ends back toward balloon tip

7. Push the Valve-Hold snugly into the cup of the white catheter.

⚠ WARNING: Proper positioning of the valve-hold within the white catheter is required to prevent inflation tube tearing.



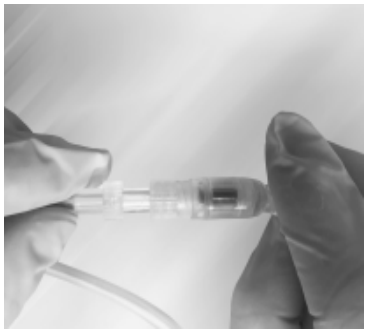
7.1 Valve-Hold



7.2 Push Valve-Hold into white cup (push straight – do not twist)

7.3 Valve-Hold inside cup

8. Connect the valve firmly to the extension tube



⚠ WARNING: If not tightened firmly the extension tube may disconnect from the valve and will require regrasping of the valve with a snare to reconnect.

Ready for use

9. Lubricate the scope and the device generously with medical jelly lubricant such as KY Jelly, over the length of the balloon, and the inflation valve.
10. Pass the endoscope and device in one hand as one unit, into the throat and advance to the esophagus and stomach as per usual endoscopic insertion.
11. Once in the gastric antrum, retroflex and confirm that the balloon has passed into the stomach.

⚠ WARNING: If the balloon is not seen on retroflexion, DO NOT INFLATE. Pull back into the esophagus and push the balloon down into the stomach with the scope tip.

12. Connect one port of the 3-way stopcock to the large syringe and a second port to the solution bag and inflate the balloon with 400-550 ml. Use sterile Normal Saline with the addition of 1% Methylene Blue solution at a concentration of 2 ml per 500 ml of Normal saline.

⚠ Caution: During inflation, if any resistance is encountered, advance the endoscope 5-10cm until the inflation flows easily.

13. After completing inflation, pull the scope back proximally to the gastro-esophageal junction.

    Note: Mild resistance is expected as the balloon tip is pulled out of the insertion facilitator

14. Place the endoscope tip next to the white catheter in the mid esophagus and leave the endoscope there.
15. Pull out the extension tube until the valve exits the mouth.
16. Grasp the valve firmly with a gauze pad while twisting off the extension tube and replacing with the white cap. Dry thoroughly and twist on the cap firmly.

⚠ Warning: The valve when wet is slippery and it may be difficult to know if it is closed firmly. Dry the valve, the cap, and your gloved fingers with a paper

towel so that you feel traction as you twist on cap firmly. If not closed firmly, the valve may leak.

17. With your fingertip in the loop of the cap, gently release the capped valve into the back of the throat.
18. Upon reaching its resting place behind the white catheter, the cap and white catheter are pushed down below the GE junction by the tip of the endoscope. After visually confirming that the cap, catheter and balloon are located below the GE junction, remove the endoscope while inspecting for tissue damage.

10.2 Recommended Medications

The following medical regimen was used during the US pivotal study and should be followed for all patients:

- Proton Pump Inhibitors (esomeprazole 20 mg per day or equivalent PPI) for the duration of Spatz3 Adjustable Balloon use
- Probiotic Acidophilus (8-10 Billion CFU) once daily for the duration of Spatz3 Adjustable Balloon use. Probiotics are recommended because the use of Proton Pump Inhibitors decreases stomach acid and could lead to bacterial growth in the stomach. The "good" probiotic bacteria are taken to counteract the possibility of other bacterial growth in the stomach.
- A combination of anti-emetic medications, Emend (125 mg day one, 80 mg days two and three) and Zofran (8 mg QID for 3 days) for the first 3 days following initial implantation

After an up-adjustment procedure (increased fluid within balloon), patients should receive the anti-emetic Zofran alone for 3 days and the PPI dose should be increased to 20 mg BID for 2 weeks.

Use of narcotics in the treatment of abdominal pain should be avoided, as it is likely to mask underlying symptoms that may delay the diagnosis of a gastric ulcer or impending gastric perforation.

Use of anti-spasmodics are recommended for the treatment of abdominal spasms.

10.3 Balloon Volume Adjustment Instructions

1. The Spatz3 Adjustable Balloon System® Adjustment/Extraction Kit, Cat. No. A-SP3-015 contains 3 extension tubes with their 3-way stopcocks, and 3 IFUs. Remove an extension tube with its 3-way stopcock. A standard rat-tooth grasping forceps should be self-supplied.

a. Ensure that the patient has been on a liquid diet for 72 hours and NPO for a minimum of 12 hours prior to attempted removal. Due to the potential for residual gastric contents in some patients, additional precautions for aspiration should be considered. Patients with signs and symptoms suggestive of gastric distention should be evaluated with physical exam and may require abdominal x-ray, nasogastric tube decompression, and in some cases general anesthesia employed.

b. Balloon Volume down-adjustment are recommended for patients who are intolerant (complaints such as nausea, vomiting, pain, or acid reflux), have failed conservative treatment with dietary change and medications, and more severe complications (pancreatitis, obstruction, etc.) have been ruled out. For such intolerance that continues more than 7-10 days beyond the first 5 days after implantation or that occurs at any time during the 8 months, the physician should consider the following recommendations for downward adjustments:

   - remove 150 mL from balloon (when initial volume was 450-550 mL).
   - remove 100 mL from balloon (when initial volume was 400 mL).

   Note that the final volume should not be reduced below 300 mL, as that may allow passage of the balloon through the pylorus which may cause an impaction and obstruction.

c. In the event of a distended balloon or an x-ray evaluation that confirms spontaneous hyperinflation (balloon hyperinflated with air), or if the balloon surface is covered with Biofilm (surface growth of colonies of organisms), perform a balloon extraction according to the instructions in section 10.4. with the following changes:

   - Drain the balloon completely and send the first 50 ml fluid for bacterial and fungal cultures.
   - Extract the balloon according to the device removal instructions in section 10.4 below
   - Ship the balloon in a sterile container to the Spatz offices for further evaluation (bacterial and fungal cultures).

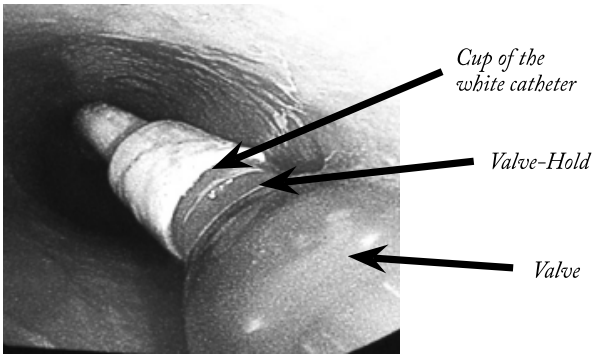
d. Balloon volume up-adjustments are recommended for patients between weeks 14-24, who have diminished balloon effect, and who are asymptomatic, with BMI above 25, and without any evidence of gastric ulcer, erosive gastritis, esophagitis (any grade).

2. Perform endoscopy and inspect for balloon or inflation tube leakage.
3. Capture the valve loop with a grasping forceps.
4. Remove the endoscope with valve pulled against the endoscope tip.

WARNING: The valve must be touching the endoscope tip during removal to prevent it from getting caught at the gastro-esophageal junction. If not closed firmly, the valve may leak.

5. Once the valve exits the mouth, the assistant secures the valve for the endoscopist.
6. Twist off the white cap from the valve and connect the valve to the provided male port of the extension tube and securely close it.

   Note: Do not lose the white cap! You will need it later.
7. Allow the extension tube to slowly slide into the throat, until the inflation tube is no longer pulling.
8. Reinsert the endoscope to confirm that: 1) the Valve-Hold and white catheter cup are touching, and 2) there are no kinks in the white catheter. (The most proximal 1 cm of the white catheter is slightly wider than the rest of the white catheter and looks like a cup).



⚠ WARNING: Never inflate/deflate unless you have an endoscopic view confirming that the Value-Hold and the white catheter cap are touching.

9. If the inflation tube or white catheter is kinked or folded, use the tip of the endoscope or movement of the extension tube to unkink.
10. Attach the Balloon Syringe and the solution bag to the 3-way stopcock and commence inflation/deflation. The final volume must be in the range 300- 850 ml.
11. When adjustment is completed, leave the endoscope in the mid-esophagus while pulling out the extension tube until the valve exits the mouth.
12. Grasp the valve while twisting off the extension tube and replace with the white cap. Dry thoroughly.

⚠ Warning: The valve when wet is slippery and it may be difficult to know if it is closed firmly. Dry the valve, the cap, and your gloved fingers with a paper towel so that you feel traction as you twist on cap firmly. If not closed firmly, the valve may leak.

13. With your fingertip in the loop of the cap, gently release the capped valve into the back of the throat.
14. Upon reaching its resting place behind the white catheter, the cap and white catheter are pushed down below the GE junction by the tip of the endoscope. After visually

confirming that the cap, catheter and balloon are located below the GE junction, remove the endoscope while inspecting for tissue damage.

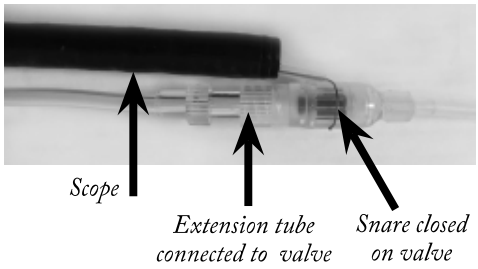
10.4 Device Removal Instructions

1. Ensure that the patient has been on a liquid diet for 72 hours and NPO for a minimum of 12 hours prior to attempted removal. Whether this regimen has been followed or not (i.e., in the case of an urgent removal), due to the potential for residual gastric contents in some patients, additional precautions for aspiration should be considered. In all patients with signs and symptoms suggestive of severely delayed gastric emptying and/or gastric outlet obstruction, a focused physical examination for abdominal distension and/or succussion splash should be performed, followed by radiographic evaluation if succession splash is absent and epigastrium full or tender. If radiographic evaluation is positive for distended stomach with or without an antral balloon, then nasogastric decompression should be considered, the airway should be secured, and general anaesthesia employed.
2. The Spatz3 Adjustable Balloon System® Adjustment/Extraction Kit, Cat. No. A-SP3-015 contains 3 extension tubes with their 3-way stopcocks, and 3 IFUs. Remove an extension tube with its 3-way stopcock. A standard rat-tooth grasping forceps should be self-supplied.
    a. In the event of balloon removal due to device defect, Spatz FGIA should be contacted, and arrangements should be made for device evaluation.
    b. In the event of spontaneous hyperinflated balloon (balloon hyperinflated with air), or if the balloon surface is covered with Biofilm (surface growth of colonies of organisms), please do the following:
        i. Drain the balloon completely and send the first 50 ml fluid for bacterial and fungal cultures.
        ii. Extract the balloon
        iii. Ship the balloon in a sterile container to the Spatz offices for further evaluation (bacterial and fungal cultures).
3. Perform endoscopy.
4. Capture the valve loop with a grasping forceps.
5. Remove the endoscope with valve pulled against the endoscope tip.

WARNING: The valve must be touching the endoscope tip during removal to prevent it from getting caught at the gastro-esophageal junction. If not closed firmly, the valve may leak.

6. Once the valve exits the mouth, the assistant secures the valve for the endoscopist.

7. Twist off the white cap from the valve
8. Insert a large polypectomy snare into the endoscope channel and perform the following actions:
    a. Open the snare.
    b. Close the snare on the middle of the valve.
    c. Connect the valve to the provided male port of the extension tube and securely close it.



9. Lower the scope with surrounding elements (as shown in photo 7c.) slowly into the back of the throat.

    > scope with snare closed on the valve.

    > extension tube connected to valve.

⚠ CAUTION: The stretched inflation tube will pull the valve down. Let it go passively. Do not push the scope.

10. Once the valve reaches the white catheter, connect the extension tube port to the suction and start deflating the balloon.
11. When completed, suction further by hand with the large syringe until it creates a vacuum.
12. Open the snare and advance over the white catheter approximately 5 cm.
13. Advance the scope below the gastro-esophageal junction to confirm complete deflation of the balloon.

⚠ CAUTION: The balloon should be compressed and empty of fluid and air.

14. Maintain the endoscope at the gastro-esophageal junction with the snare fully open while pulling the extension tube until the valve exits the mouth.

    Note: This will pull the balloon into the open snare.

15. Close the snare on the white catheter-balloon junction

    Note: Close the snare on the distal 2 mm of the white catheter (firm part of catheter) with or without balloon material included.

16. Pull the snare so that the balloon is touching the tip of the endoscope, and maintain the inflation tube stretched with the valve outside of the mouth.
17. Remove the endoscope with stretched inflation tube together in one hand, while the snare is maintained at channel opening by left hand.

    CAUTION: The inflation tube must stay stretched during extraction – do not let it slip back.

18. Hyperextension of the neck of the patient can help with removal as the device passes through the upper esophageal sphincter.
19. Reinsert the scope and inspect the esophagus and stomach for tissue damage.

11. RESULTS FROM THE US PIVOTAL STUDY

The purpose of the US Pivotal study was to evaluate the safety and effectiveness of the Spatz3 Adjustable Balloon in subjects with a BMI ≥30 and <40 kg/m^2 who failed to achieve and maintain weight-loss with a weight control program. Subjects were studied in a randomized, controlled, multi-center study. The control group was to receive dietary/exercise counselling for 32 weeks. The treatment group was to receive dietary/exercise counselling plus the Spatz3 Adjustable Balloon for 32 weeks, followed by a 24-week follow up period.

The Spatz3 US Pivotal Study subject cohort consisted of 288 subjects who were randomized 2:1 to treatment (balloon) and control. 187 subjects were randomized to receive the balloon and 101 subjects were randomized to the control arm of the study. Subjects and investigators were not blinded. Only clinical staff taking weight measurements were blinded. All treatment group subjects were to undergo endoscopy and those without endoscopic contraindications were to be implanted with the Spatz3 Adjustable Balloon for 32 weeks. All subjects were to follow a 1000-1200 kcal/day-deficit diet during their participation in the study; however, compliance was not evaluated.

Of the 187 subjects who received a balloon, 156 (83%) completed week 32 and 31 (17%) needed an early balloon removal, most of them due to adverse events (26/187 or 14%). Of the 101 subjects who were randomized to the control group, 75 (75%) completed week 32 and 26 (26%) withdrew early. The 187 treatment group subjects were asked to remain in the 6-month follow-up phase regardless of when their balloon was extracted. Of those, 37 (20%) dropped out early, and 150 (80%) completed 6-month follow-up.

The intent-to-treat (ITT) population included the 288 subjects randomized, while the Per-Protocol population includes 202 subjects (132 treatment and 70 control) who were not excluded for one of the following reasons:

- Did not meet the inclusion criterion of baseline BMI ≥ 30kg/m^2 and < 40 kg/m^2
- Did not receive the treatment he/she was randomized to
- Early balloon removal or early discontinuation from control group
- More than three missed or significantly out of window visits before week 32 (missed visits after week 32 are not relevant because this population will only be used for the primary endpoints analyses).
- Non-compliance with the volume addition/removal requirements

Table 2 provides a summary of the subject demographics and baseline characteristics for the subjects in the US Pivotal Clinical Study.

Table 2. Subject demographics and baseline characteristics (US Pivotal Study)

Characteristic	ITT Population		
	Control	**Balloon**	**All Subjects**
Age (years) – Mean (range)	44.0 (24.0-64.0)	44.4 (22.0-64.0)	44.3 (22.0-64.0)
Weight (lb) – Mean (range)	216.4 (161-300)	216.3 (161-297)	216.4 (161-300)
Height (in) – Mean (range)	65.1 (59.0-73.0)	65.1 (58.5-73.0)	65.1 (58.5-73.0)
BMI (kg/m^2)	35.8 (30.3-40.9)	35.8 (30.2-40.3)	35.8 (30.2-40.9)
Sex – n (%)			
Female	90 (89%)	162 (87%)	252 (88%)
Male	11 (11%)	25 (13%)	36 (13%)
Race – n (%)			
White	72 (71%)	132 (71%)	204 (71%)
Black or African American	26 (26%)	49 (26%)	75 (26%)
Asian	1 (1%)	1 (1%)	2 (1%)
Native Hawaiian or Pacific Islander		1 (1%)	1 (0%)
None of the above	1 (1%)	3 (2%)	4 (1%)
Unknown	1 (1%)	1 (1%)	2 (1%)
Ethnicity – n (%)			
Hispanic or Latino	8 (8%)	10 (5%)	18 (6%)
Not Hispanic or Latino	92 (91%)	173 (93%)	265 (92%)
Unknown	1 (1%)	4 (2%)	5 (2%)
Medical History			
Hypertension – n (%)	32 (32%)	41 (22%)	73 (25%)
Diabetes – n (%)	4 (4%)	13 (7%)	17 (6%)
Sleep Apnea – n (%)	1 (1%)	1 (1%)	2 (1%)
Elevated Lipids – n (%)	23 (23%)	41 (22%)	64 (22%)

At 18 weeks ±4 weeks, treatment group subjects were evaluated, and those that met the criteria in Table 3 below were to undergo an adjustment procedure wherein the balloon volume was increased to achieve extra weight loss. The balloon adjustment procedure was done with an endoscopy procedure under the same sedation as the implantation procedure. At the end of the 32-week treatment period the control subjects were dismissed, and the treatment group was explanted and completed a 24-week follow up.

Table 3. Week 18 Balloon Adjustment Algorithm

Subject Status	Week 18 Upward Balloon Adjustment
Reached goal weight (calculated by maximum BMI of 25 kg/m^2) without any symptoms of GE reflux or symptoms suggestive of gastritis or gastric ulcer	No adjustment (No Week 18 endoscopy performed)
Gastric ulcer identified by a prior unscheduled endoscopy	No adjustment (No additional endoscopy besides the follow-up endoscopies to confirm healing, per the protocol)
Gastric ulceration or esophagitis found at Week 18 endoscopy	No adjustment (investigator decided if balloon required extraction)
No gastric ulceration, esophagitis, or erosive gastritis found at Week 18 endoscopy (non-erosive gastritis permitted)	• No addition if GE reflux was not controlled by medication • 200 mL if subject was previously down adjusted for intolerance but was asymptomatic at Week 18 • 200 mL for any height patient with GE reflux controlled by medication • 250 mL for patient with height <64 inches without GE reflux • 300 mL for patient with height ≥64 inches without GE reflux Maximum final volume did not exceed 850 mL

11.1 Safety Results

11.1.1 Serious Adverse Events

Ten (5.3%) treatment group subjects experienced 29 serious adverse events (SAEs), while one control subject (1%) experienced one SAE. There were 24 device-related SAEs in 7 out of 187 treatment group subjects. The incidence of device-related SAEs was 3.7% (7/187, 95% C.I. 1.5%, 7.8%). An incidence of esophageal mucosal tear was also related to the device placement procedure. Out of the 7 subjects with serious side effects, four subjects had an early balloon removal. All related SAEs were classified to the Gastrointestinal disorders and Metabolism and nutritional disorders system organ classes. The most frequent SAEs were nausea, vomiting, and abdominal pain. Additional details are provided in Table 4.

Table 4. Device and Procedure Related Serious Adverse Events

Event	Device or Procedure Related*	Subjects with SAE** (% of All treatment Subjects)	Events	Onset (Days to Event)	% of Subjects with SAE that had Balloon Removed
Nausea	Device	6/187 (3.2%)	7	Mean = 84.6 days Median = 131 days Range = 0-150 days	2/6 (33%)
Vomiting	Device	5/187 (2.7%)	5	Mean = 90.4 days Median = 131 days Range = 1-150 days	2/5 (40%)
Abdominal pain	Device	4/187 (2.1%)	4	Mean = 9.8 days Median = 1 days Range = 0-37 days	2/4 (50%)
Dehydration	Device	3/187 (1.6%)	3	Mean = 92.7 days Median = 131 days Range = 7-140 days	1/3 (33%)
Diarrhea	Device	2/187 (1.1%)	2	Mean = 75.5 days Median = 76 days Range = 1-150 days	0/2 (0%)
Gastroesophageal reflux disease	Device	1/187 (0.5%)	1	Mean = 37.0 days Median = 37 days Range = 37-37 days	1/1 (100%)
Failure to thrive***	Device	1/187 (0.5%)	1	Mean = 7.0 days Median = 7 days Range = 7-7 days	1/1 (100%)
Hypokalemia	Device	1/187 (0.5%)	1	Mean = 150.0 days Median = 150 days Range = 150-150 days	0/1 (0%)
Esophageal Mucosal Tear	Device and Procedure	1/187 (0.5%)	1	Mean = 0 days Median = 0 days Range = 0-0 days	1/1(100%)

* A device-related adverse event was a result of device use; whereas a procedure-related adverse event was a result of the endoscopic procedure. An adverse event can be related to the device, procedure, both, or neither.

** An SAE is defined as an untoward event that: results in death; is life-threatening; requires inpatient hospitalization or prolongation of an existing hospitalization; results in persistent or significant disability or incapacity; is associated with a congenital anomaly or birth defect; or qualifies as “other” medically significant event.

***Failure to thrive defined as overall weakness and resulted from the following AEs: Nausea, Vomiting, Dehydration, Abdominal pain

11.1.2 Adverse Events

A total of 2,522 device-related adverse events were reported. The majority of events were mild in severity (71.1%, 1,561/2,522). There were 446 moderate severity events (20.3%%) and 179 severe events (8.1%).

Almost all treatment group subjects (183/187, 98%) experienced gastrointestinal AEs, with nausea, dyspepsia and vomiting being the most frequent (90% (169/187), 74% (137/187), and 72% (134/187) of subjects, respectively). Ten (10) of the 187 treatment group subjects (5.3%) required intravenous fluid infusion or intramuscular injections of Phenergan for severe nausea and vomiting. In other system organ classes headache (44/187, 24%), hiccups (63/187, 34%), dizziness (40/187 21%), and dehydration (38/187, 20%) were the most frequent. Though not associated with an adverse event, one balloon deflation was observed at the time of balloon removal (1/187, 0.5%). The suspected reason for the deflation was the presence of a fungus biofilm on the surface of the balloon.

Table 5. Device and Procedure-Related GI Adverse Events Occurring in >10% of the Spatz3 Adjustable Balloon -Treatment Subjects

Device- or Procedure-Related Adverse Event	Subjects (% of Treatment Subjects) N=187	Day of Onset Median (Mean) Range	Duration (days) Median (Mean) Range	Severity n/N (%) Mild Moderate Severe	Subjects with Onset </= 3 Days Post-Implantation		
					Any Duration (% of Treatment Subjects)	Duration 14-30 Days (% of </= 3 Days)	Duration >30 Days (% of </= 3 Days)
Nausea	169 (90.4%)	19 (62.7) 0-381	6 (17.7) 0-217	66/169 (39.1%) 62/169 (36.7%) 41/169 (24.3%)	152 (89.9%)	7 (4.6%)	13 (8.6%)
Dyspepsia	137 (73.3%)	18 (68.8) 0-385	14 (28.3) 0-247	64/137 (46.7%) 52/137 (38.0%) 21/137 (15.3%)	106 (77.4%}	16 (15.1%)	10 (9.4%)
Vomiting	134 (71.7%)	28 (68.1) 0-381	3 (12.8) 0-154	67/134 (50.0%) 37/134 (27.6%) 30/134 (22.4%)	79 (59.0%}	4 (5.1%)	5 (6.3%)
Eructation	121 (64.7%)	23 (55.0) 0-385	40 (60.9) 0-291	95/121 (78.5%) 19/121 (15.7%) 5/121 (4.1%)	79 (65.3%}	12 (15.2%)	32 (40.5%)
Abdominal pain	113 (60.4%)	10 (58.3) 0-384	8 (20.4) 0-366	49/113 (43.4%) 44/113 (38.9%) 20/113 (17.7%)	92 (81.4%}	12 (13.0%)	14 (15.2%)
Constipation	95 (50.8%)	27 (71.8) 0-398	24 (34.1) 0-239	79/95 (83.2%) 12/95 (12.6%) 3/95 (3.2%)	42 (44.2%}	6 (14.3%)	11 (26.2%)
Diarrhea	73 (39.0%)	43 (81.8) 0-349	5 (16.7) 0-147	44/73 (60.3%) 23/73 (31.5%) 6/73 (8.2%)	18 (24.7%}	4 (22.2%)	1 (5.6%)

Device- or Procedure-Related Adverse Event	Subjects (% of Treatment Subjects) N=187	Day of Onset Median (Mean) Range	Duration (days) Median (Mean) Range	Severity n/N (%) Mild Moderate Severe	Subjects with Onset </= 3 Days Post-Implantation		
					Any Duration (% of Treatment Subjects)	Duration 14-30 Days (% of </= 3 Days)	Duration >30 Days (% of </= 3 Days)
Breath odor	61 (32.6%)	29 (69.3) 0-314	27 (45.1) 0-275	57/61 (93.4%) 2/61 (3.3%) 1/61 (1.6%)	28 (45.9%}	5 (17.9%)	10 (35.7%)
Abdominal rigidity	38 (20.3%)	0 (51.6) 0-231	7 (13.3) 0-123	24/38 (63.2%) 13/38 (34.2%) 1/38 (2.6%)	34 (89.5%}	2 (5.9%)	4 (11.8%)
Abdominal distension	29 (15.5%)	11 (50.9) 0-331	29 (66.5) 1-300	23/29 (79.3%) 4/29 (13.8%) 2/29 (6.9%)	13 (44.8%}	4 (30.8%)	6 (46.2%)
Gastroesophageal reflux disease	19 (10.2%)	43 (70.8) 0-274	21 (31.0) 0-96	10/19 (52.6%) 5/19 (26.3%) 4/19 (21.1%)	4 (21.1%}	0 (0%)	1 (25.0%)

Table 6. Number of Subjects (%) Experiencing Device and/or Procedure-related Adverse Events by Standard Term and Maximum Severity (Safety Population)

	Severity (N = 187)			
	Mild	Moderate	Severe	Total
Total	**179 (96%)**	**125 (67%)**	**71 (38%)**	**183 (98%)**
Gastrointestinal disorders	**177 (95%)**	**123 (66%)**	**70 (37%)**	**183 (98%)**
Nausea	67 (36%)	62 (33%)	40 (21%)	169 (90%)
Dyspepsia	63 (34%)	52 (28%)	21 (11%)	136 (73%)
Vomiting	67 (36%)	37 (20%)	30 (16%)	134 (72%)
Eructation	95 (51%)	19 (10%)	5 (2.7%)	121 (65%)
Abdominal pain	49 (26%)	44 (24%)	20 (11%)	113 (60%)
Constipation	79 (42%)	12 (6.4%)	3 (1.6%)	95 (51%)
Diarrhea	43 (23%)	23 (12%)	6 (3.2%)	72 (39%)
Breath odor	57 (30%)	2 (1.1%)	1 (0.5%)	61 (33%)
Abdominal rigidity	24 (13%)	13 (7.0%)	1 (0.5%)	38 (20%)
Abdominal distension	23 (12%)	4 (2.1%)	2 (1.1%)	29 (16%)
Gastroesophageal reflux disease	9 (4.8%)	5 (2.7%)	4 (2.1%)	18 (9.6%)
Esophagitis	5 (2.7%)	6 (3.2%)	2 (1.1%)	13 (7.0%)
Gastritis	5 (2.7%)	0	0	5 (2.7%)
Flatulence	3 (1.6%)	4 (2.1%)	1 (0.5%)	8 (4.3%)
Regurgitation	6 (3.2%)	0	0	6 (3.2%)
Esophageal mucosal tear	2 (1.1%)	2 (1.1%)	0	4 (2.1%)

Gastritis erosive	3 (1.6%)	0	0	3 (1.6%)
Dry mouth	3 (1.6%)	1 (0.5%)	0	4 (2.1%)
Gastric ulcer	2 (1.1%)	2 (1.1%)	0	4 (2.1%)
Retching	2 (1.1%)	0	0	2 (1.1%)
Hematemesis	1 (0.5%)	0	1 (0.5%)	2 (1.1%)
Esophageal bleeding*	2 (1.1%)	0	0	2 (1.1%)
Hematochezia	0	1 (0.5%)	0	1 (0.5%)
Hyperchlorhydria	2 (1.1%)	0	0	2 (1.1%)
Salivary hypersecretion	1 (0.5%)	0	0	1 (0.5%)
Proctalgia	1 (0.5%)	0	0	1 (0.5%)
Oral disorder	1 (0.5%)	0	0	1 (0.5%)
Nervous system disorders	**60 (32%)**	**11 (5.9%)**	**2 (1.1%)**	**70 (37%)**
Headache	37 (20%)	6 (3.2%)	0	44 (24%)
Dizziness	33 (18%)	5 (2.7%)	1 (0.5%)	40 (21%)
Migraine	1 (0.5%)	0	0	1 (0.5%)
Syncope	0	0	1 (0.5%)	1 (0.5%)
Tremor	1 (0.5%)	0	0	1 (0.5%)
Dysgeusia	1 (0.5%)	0	0	1 (0.5%)
Respiratory, thoracic and mediastinal disorders	**61 (33%)**	**10 (5.3%)**	**2 (1.1%)**	**73 (39%)**
Hiccups	52 (28%)	9 (4.8%)	2 (1.1%)	63 (34%)
Oropharyngeal pain	5 (2.7%)	1 (0.5%)	0	6 (3.2%)
Cough	2 (1.1%)	0	0	2 (1.1%)
Dyspnea	2 (1.1%)	0	0	2 (1.1%)
Throat irritation	2 (1.1%)	0	0	2 (1.1%)
Hemoptysis	1 (0.5%)	0	0	1 (0.5%)
Dry throat	1 (0.5%)	0	0	1 (0.5%)
Aspiration	1 (0.5%)	0	0	1 (0.5%)
Metabolism and nutrition disorders	**39 (21%)**	**18 (9.6%)**	**10 (5.3%)**	**66 (35%)**
Dehydration	17 (9.1%)	12 (6.4%)	9 (4.8%)	38 (20%)
Concentrated urine*	19 (10%)	7 (3.7%)	0	26 (14%)
Decreased appetite	3 (1.6%)	0	0	3 (1.6%)
Hypokalemia	0	0	1 (0.5%)	1 (0.5%)
Failure to thrive	0	0	1 (0.5%)	1 (0.5%)
Hypocalcemia	0	0	1 (0.5%)	1 (0.5%)
General disorders and administration site conditions	**21 (11%)**	**6 (3.2%)**	**5 (2.7%)**	**29 (16%)**
Fatigue	13 (7.0%)	4 (2.1%)	3 (1.6%)	20 (11%)
Chest pain	2 (1.1%)	1 (0.5%)	3 (1.6%)	6 (3.2%)
Asthenia	1 (0.5%)	2 (1.1%)	1 (0.5%)	4 (2.1%)
Pyrexia	2 (1.1%)	0	0	2 (1.1%)
Chest discomfort	3 (1.6%)	1 (0.5%)	0	4 (2.1%)
Sensation of foreign body	4 (2.1%)	0	0	4 (2.1%)
Hunger	1 (0.5%)	0	0	1 (0.5%)
Malaise	1 (0.5%)	0	0	1 (0.5%)

Musculoskeletal and connective tissue disorders	**12 (6.4%)**	**2 (1.1%)**	**1 (0.5%)**	**15 (8.0%)**
Muscle spasms	9 (4.8%)	0	0	9 (4.8%)
Back pain	3 (1.6%)	1 (0.5%)	1 (0.5%)	5 (2.7%)
Musculoskeletal chest pain	0	1 (0.5%)	0	1 (0.5%)
Skin and subcutaneous tissue disorders	**1 (0.5%)**	**1 (0.5%)**	**0**	**2 (1.1%)**
Erythema	1 (0.5%)	0	0	1 (0.5%)
Skin exfoliation	0	1 (0.5%)	0	1 (0.5%)
Psychiatric disorders	**1 (0.5%)**	**0**	**1 (0.5%)**	**2 (1.1%)**
Anxiety	1 (0.5%)	0	1 (0.5%)	2 (1.1%)
Renal and urinary disorders	**0**	**1 (0.5%)**	**0**	**1 (0.5%)**
Nephrolithiasis	0	1 (0.5%)	0	1 (0.5%)
Investigations	**1 (0.5%)**	**0**	**0**	**1 (0.5%)**
Blood pressure increased	1 (0.5%)	0	0	1 (0.5%)
Eye disorders	**3 (1.6%)**	**0**	**0**	**3 (1.6%)**
Vision blurred	1 (0.5%)	0	0	1 (0.5%)
Dry eye	1 (0.5%)	0	0	1 (0.5%)
Visual impairment	1 (0.5%)	0	0	1 (0.5%)
Blood and lymphatic system disorders	**1 (0.5%)**	**0**	**0**	**1 (0.5%)**
Iron deficiency anemia	1 (0.5%)	0	0	1 (0.5%)

11.1.3 Downward Adjustments and Device Removals

Twenty-eight treatment group subjects (28/187, 15%) received downward adjustments as a result of adverse events. The proportion of subjects with downward adjustments increased with the initial balloon volume (from 0/14 (0%) with 400 ml to 19/97 (19.6%) with 550 ml). The mean time between implantation and downward adjustment across initial volume subgroups was 98 to 106 days (Table 7). Nausea, vomiting, and dyspepsia were the most frequent AEs that triggered adjustments.

Table 7. Summary of Downward Volume Adjustments Due to Adverse Events by Initial Balloon Volume

Initial Volume (ml)	**All Subjects N (% of 187)**	**Down-Adjusted Subjects N (% of # at initial volume)**	**Days After Implant Mean ± SD Median (Min-Max)**	**Volume Decreased (ml) Mean ± SD Median (Min-Max)**	**Subjects with Adverse Events with Action = 'Decreased Volume' N (% of down adjusted subjects)**
400	14 (7%)	0 (0.0%)	n/a	n/a	n/a

Initial Volume (ml)	**All Subjects N (% of 187)**	**Down-Adjusted Subjects N (% of # at initial volume)**	**Days After Implant Mean ± SD Median (Min-Max)**	**Volume Decreased (ml) Mean ± SD Median (Min-Max)**	**Subjects with Adverse Events with Action = 'Decreased Volume' N (% of down adjusted subjects)**
450	44 (24%)	5 (11.4%)	101±74 134 (21-175)	165±49 150 (125-250)	Nausea: 4 (80%) Vomiting: 4 (80%) Dyspepsia: 3 (60%) Abdominal pain: 2 (40%) Concentrated urine*: 1 (20%) Constipation: 1 (20%) Diarrhea: 1 (20%) Fatigue: 1 (20%)
500	32 (17%)	4 (12.5%)	106±65 137 (9-142)	150±0 150 (150-150)	Dehydration: 1 (25%) Dyspepsia: 1 (25%) Nausea: 1 (25%) Vomiting: 1 (25%)
550	97 (52%)	19 (19.6%)	98±52 119 (8-168)	166±50 150 (100-300)	Vomiting: 13 (68%) Nausea: 12 (63%) Dyspepsia: 7 (37%) Eructation: 6 (32%) Abdominal pain: 5 (26%) Breath odor: 3 (16%) Abdominal distension: 2 (11%) Hiccups: 2 (11%) Constipation: 1 (5%) Dehydration: 1 (5%) Diarrhea: 1 (5%) Dizziness: 1 (5%) Headache: 1 (5%)

Initial Volume (ml)	All Subjects N (% of 187)	Down-Adjusted Subjects N (% of # at initial volume)	Days After Implant Mean ± SD Median (Min-Max)	Volume Decreased (ml) Mean ± SD Median (Min-Max)	Subjects with Adverse Events with Action = 'Decreased Volume' N (% of down adjusted subjects)
All	187 (100%)	28 (15.0%)	100±56 127 (8-175)	163±45 150 (100-300)	Vomiting: 18 (64%) Nausea: 17 (61%) Dyspepsia: 11 (39%) Abdominal pain: 7 (25%) Eructation: 6 (21%) Breath odor: 3 (11%) Abdominal distension: 2 (7%) Constipation: 2 (7%) Dehydration: 2 (7%) Diarrhea: 2 (7%) Hiccups: 2 (7%) Concentrated urine*: 1 (4%) Dizziness: 1 (4%) Fatigue: 1 (4%) Headache: 1 (4%)

There were 50 treatment group subjects (50/187, 27%) who had AEs and requested balloon removal. Twenty-eight of them (28/50, 56%) had a downward volume adjustment (Table 7). Of these 28 subjects who had downward adjustments, 21 completed the 8-month balloon implantation procedure and thus avoided an early explant. Of the 31 subjects who had an early explant, 29 were due to AEs, 1 to pregnancy, and 1 to relocation (Table 8).

Table 8. Early Explants by Reason and Downward Volume Adjustment

Reason for requested explant	Number pf patients requested explant	Number of patients who had down adjustment	Early explants conducted	Early explants avoided
Adverse events	50/187 (27%)	28/50 (15%)	29/50 (58%)	21/50 (42%)
Pregnancy	1/187 (0.5%)	0/187 (0%)	1/1 (100%)	0/1 (0%)
Relocation	1/187 (0.5%)	0/187 (0%)	1/1 (100%)	0/1 (0%)
Total	52/187 (28%)	28/187 (15%)	31/52 (60%)	21/52 (40%)

Table 9 provides a summary of early explants by initial balloon volume. Eleven of the 31 early explanted-subjects had abnormal endoscopic findings in the esophagus and 6 in the stomach. There wasn't a clear trend towards a higher proportion of early explants or a higher incidence of endoscopic findings with increasing initial balloon volume.

Table 9. Summary of Early Explants by Initial Balloon Volume

Initial Volume (ml)	**All Subjects N (% of 187)**	**Early Explanted Subjects N (% of #at initial volume)**	**Days After Implant Mean ± SD Median (Min-Max)**	**Reasons for Removal**	**Total # of Endoscopic findings at early explant**
400	14 (7%)	1 (7.1%)	7±0 7 (7-7)	Adverse event: 1	None
450	44 (24%)	6 (13.6%)	132±46 146 (40-165)	Adverse event: 5 Subject's decision: 1	Esophagus abnormal: 4 Esophagitis grade 1 or 2: 1 Esophagitis grade 3 or 4: 2 Barrett's esophagus: 1 Stomach abnormal: 1 Erosive Gastritis: 1
500	32 (17%)	8 (25.0%)	71±73 46 (2-203)	Adverse event: 6 Relocation: 1 Subject's decision: 1	Esophagus abnormal: 1 Esophagitis grade 1 or 2: 1
550	97 (52%)	16 (16.5%)	64±64 34 (1-168)	Adverse event: 14 Pregnancy: 1 Subject's decision: 1	Esophagus abnormal: 6 Esophagitis grade 1 or 2: 2 Esophagitis grade 3 or 4: 2 Stomach abnormal: 5 Non-erosive gastritis: 4 Gastric ulcer: 1 Pyloric ulcer: 1
All	187 (100%)	31 (16.6%)	77±67 54 (1-203)	Adverse event: 26 Pregnancy: 1 Relocation: 1 Subject's decision: 3	Esophagus abnormal: 11 Esophagitis grade 1 or 2: 4 Esophagitis grade 3 or 4: 4 Barrett's esophagus: 1 Stomach abnormal: 6 Erosive Gastritis: 1 Non-erosive gastritis: 4 Gastric ulcer: 1 Pyloric ulcer: 1

11.2 Effectiveness

11.2.1 Primary Effectiveness Endpoint Results

The Study had two co-primary effectiveness endpoints:

- Percent total body weight loss (%TBL) at 32 weeks; and
- Clinical response, where a responder is defined as a subject with at least a 5% TBL at 32 weeks

The Intent-to-Treat (ITT) population included all 288 randomized subjects according to each subject's randomized treatment group. The Per Protocol population included all ITT population subjects except those who had significant protocol deviations.

The co-primary hypotheses based on the Intent-to-Treat (ITT) population were as follows:

1. The mean %TBL in the Spatz3 group exceeds that in the control group by 4.5%.

   $H_O: \mu_S - \mu_C \leq 4.5\%$ vs. $H_A: \mu_S - \mu_C > 4.5\%$,

   where μ_S and μ_C are the population mean %TBL for the Spatz3 and control groups, respectively.

2. The response rate in the Spatz3 group is superior to a performance goal of 50%, where a responder is defined as a ≥5% TBL at 32 weeks.

   $H_O: \pi \leq 50\%$ vs. $H_A: \pi > 50\%$,

   where π is the population response rate in the Spatz3 group.

To compare the Week 32 %TBL between the treatment and control groups, a linear model was fitted. This model had terms for the treatment group, site, baseline BMI, and sex, and was run on three datasets of Week 32 blinded weights:

- an ITT population dataset in which missing Week 32 weights were imputed through a multiple imputation procedure,
- an ITT population dataset in which missing Week 32 weights were imputed through a last observation carried forward (LOCF) procedure, and
- the Per-Protocol population (PPP) dataset.

Total Body Weight Loss

The Spatz3 Adjustable Balloon study met its first co-primary endpoint for all three datasets (Table 10). At Week 32 the difference between the treatment and control mean %TBLs predicted by the linear model from the multiply-imputed ITT population dataset was 11.7%, and its 97.5% lower confidence bound was 9.9%. As this exceeds the pre-specified super-superiority margin of 4.5%, the combination of Spatz3 Adjustable Balloon and dietary counseling is deemed to have super-superiority over dietary counseling alone. The same conclusion was obtained from the LOCF-imputed ITT population dataset (difference between predicted means = 10.7% and lower confidence bound 9.0%) and from the per-protocol population dataset (difference between predicted means = 11.1% and lower confidence bound 9.2%).

Table 10. Total Body Loss (%TBL) at Week 32

	Treatment[1]	Control	Treatment – Control Difference			
	Mean (SD, min-max)	Mean (SD, min-max)	ΔMeans	ΔLSMeans[2]	97.5% LCB[3]	p
%TBL – ITT - Multiple Imputation	15.0% (7.7%, -1.9%-34.7%)	3.3% (6.7%, -19.0%-21.7%)	11.7%	11.7%	9.9%	<0.0001
%TBL – ITT - LOCF	13.8% (7.5%, -0.5%-32.8%)	3.1% (5.5%, -6.7%-21.7%)	10.7%	10.7%	9.0%	<0.0001
%TBL - PPP – No Imputation	15.2% (6.9%, 1.4%-32.8%)	4.1% (5.9% -6.7%-21.7%)	11.1%	11.1%	9.2%	<0.0001

1 – 100 control subjects are included in the analysis though 101 in total were enrolled because necessary information was not collected from 1 subject necessary to fit the statistical analysis model.

2 - Difference between means predicted by a statistical model with factors for treatment, site, sex, and baseline BMI.

3 - 97.5% lower confidence bound for the difference between the model-predicted means.

Responder Analysis

The Spatz3 Adjustable Balloon Study also met its second co-primary effectiveness endpoint. The three datasets mentioned above were used to calculate the proportion of responders, i.e., treatment group subjects whose Week 32 %TBL exceeded 5% TBL, and an exact 97.5% lower confidence bound for that proportion. These proportions (91.7%, 87.7%, and 96.2% from the multiply-imputed ITT population, LOCF-imputed ITT population, and PPP datasets, respectively) and their lower confidence bounds (87.2%, 82.1%, and 91.4%) were above the pre-specified performance goal of 50% (Table 11).

Table 11. Response Rate (%TBL≥5%) in Treatment Group at Week 32

	All Treatment Subjects		Responders (%TBL≥5%)		
	N	Mean %TBL	N	Proportion	97.5% LCB
ITT - Multiple Imputation	187	15.0%	171.4[1]	91.7%	87.2%
ITT - LOCF	187	13.8%	164	87.7%	82.1%
PPP – No Imputation	132	15.2%	127	96.2%	91.4%

1 Mean of the five counts from the five multiply-imputed datasets

11.2.2 Secondary Effectiveness Endpoints

The study had two prespecified secondary endpoints.

Maintenance of Weight Loss

The first secondary endpoint was the proportion of treatment group subjects who, by the end of the 6-month post-removal follow-up, had maintained ≥40% of the weight loss they had achieved by the balloon extraction date. This analysis was conducted on treatment group subjects who completed week 56 regardless of their protocol compliance (150 treated subjects completed week 56 of the study). Subjects who had an early balloon removal were included (if they completed the 6-month follow-up) and two analyses were performed:

a) using the actual post-extraction weight on the extraction day,

b) and using their imputed week 32 weight (the mean of the 5 imputed week 32 weights").

The proportion calculated from the non-imputed ITT population dataset was 74.0% excluding subjects with missing weight measurements. The proportion from the multiply-imputed ITT population dataset was 73.3%" (Table 12).

Table 12. Weight Loss Maintenance 6 Months Post Balloon Removal – ITT Population

	Responders (Preserved ≥40% of weight loss)	
	N	**Proportion**
Post-extraction weight on the extraction day	111	74.0% (111/150)
Multiply-imputed Week 32 visit weight	110	73.3% (110/150)

Excess Weight Loss

The second secondary endpoint was proportion of balloon group subjects that achieved percent excess weight loss (%EWL) ≥ 25% at 32 weeks. Excess Body Weight Loss (EWL), which assumes an ideal BMI of 25 kg/m^2 and uses height (h) measured in inches, was calculated as follows:

$$Ideal\ Weight\ (lb) = \frac{25\ x\ h^2}{703}$$

$$Excess\ Weight\ (lb) = Day\ 0\ weight\ (lb) - Ideal\ Weight\ (lb)$$

$$\%EWL = \frac{TBL\ (lb)}{Excess\ Weight\ (lb)}\ x\ 100\%$$

The proportion of subjects with EWL ≥ 25% was calculated from the multiply-imputed ITT population dataset (Table 13).

Table 13. Response Rate (EWL≥25%) at Week 32 – ITT Population

	All Treatment Subjects		**Responders (EWL≥25%)**	
	N	**Mean %EWL**	**N**	**Proportion**
Multiple Imputation	187	53.6%	157	84.0%

12. WARRANTY AND LIMITATION OF WARRANTY

Spatz FGIA, Inc. warrants that reasonable care was used in the design and manufacture of this product. Because Spatz FGIA, Inc. has no control over the conditions of use, patient selection or handling of the device after it leaves its possession, Spatz FGIA, Inc. does not warrant either a good effect or against an ill effect following its use. Spatz FGIA, Inc. shall not be directly or indirectly responsible for any incidental or consequential loss, damage or expenses directly or indirectly arising from the use of this product. Spatz FGIA, Inc.'s SOLE responsibility in the event Spatz FGIA, Inc. determines the product was defective when shipped by Spatz FGIA, Inc., shall be the replacement of the product. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including but not limited to any implied warranties of merchantability or fitness for use.

13. PRODUCT SPECIFICATIONS

Spatz3 Adjustable Balloon System® Insertion Kit, Catalog No. A-SP3US-03K includes the following components: Balloon, 50-60 ml syringe, white cap, extension tube and 3-way stopcock, and insertion facilitator.

The Spatz3 Adjustable Balloon System® Adjustment/Extraction Kit, Cat. No. A-SP3-015 contains 3 extension tubes with their 3-way stopcocks and 3 IFUs.

The products have been assembled in a clean room and are supplied non-sterile and packaged ready for use.

For additional information, please contact your local distributor or:

Spatz FGIA, Inc
1801 S Perimeter Rd
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Fort Lauderdale, FL 33309
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www.spatzmedical.com
info@spatzmedical.com

REF	Device reference number		Manufacturer	Rx only	The device is restricted to sale by or on the order of a physician
LOT	Lot number in the format of LLLLLL		Attention, see instructions for use		Do not reuse
	Manufacturing date in the format of YYYY-MM	NON STERILE	Non-sterile	Not made with natural rubber latex	
	2-year expiry date, based on the manufacturing date, in the format of YYYY-MM	86F 60F	Limits of temperature	STERILE EO	Syringe sterilized using ethylene oxide

14. MR SAFETY INFORMATION

Non-clinical testing demonstrated that the Spatz3 Adjustable Balloon is MR Conditional. A patient with this device can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 2,000-Gauss/cm (20-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode).

Under the scan conditions defined above, the Spatz3 Adjustable Balloon System is expected to produce a maximum temperature rise of less than 2ºC after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the Spatz3 Adjustable Balloon extends approximately 10-mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.