Patient Information Booklet for the Spatz3 Adjustable Balloon

Please review this information before your procedure.
Please talk to your doctor if you have any questions or do not understand any of this information.

The Spatz3 Adjustable Balloon Procedure is only available by prescription from a doctor.

Contents

Glossary

Body Mass Index (BMI): A measure of body fat based upon height and weight which is used to tell if your weight is in a healthy range.

- If your BMI is less than 18.5, it falls within the underweight range.
- If your BMI is 18.5 to <25, it falls within the normal.
- If your BMI is 25.0 to <30, it falls within the overweight range.
- If your BMI is 30.0 or higher, it falls within the obese range.

Obesity is frequently subdivided into categories:

- Class 1: BMI of 30 to < 35
- Class 2: BMI of 35 to < 40
- Class 3: BMI of 40 or higher. Class 3 obesity is sometimes categorized as “extreme” or “severe” obesity.

Bowel Obstruction: A possibly serious problem with your body where the intestines are blocked and bowel surgery may be required. If they become blocked, food, drinks, and bowel fluids cannot pass through the body.
Clinical Study: A scientific trial to test new medicines or medical devices in a controlled way to find out how well they work and what risks are associated with their use.
Endoscopy: A medical test where your doctors look inside your body using an endoscope.
Endoscope: A long, bendable tube with a tiny camera attached. The doctor moves it down your throat to see inside your digestive tract which includes the esophagus, stomach, small intestine, and colon.
Esophagus: The tube that carries food and liquids from your mouth to your stomach.
Gallstones: Stones that form in the gallbladder (a small organ where fluid from the liver, bile, is stored), which can cause a painful digestive problem.
Nutritionist/Dietician: A trained person who helps others plan what foods to eat that are good for their health.
Obesity: A medical condition in which extra body fat builds up to the point that it may be unhealthy. People with a BMI of 30 and above have obesity.
Intragastric Balloon (IGB): A balloon made of a soft, rubber-like material used to help with weight loss. It is designed to take up space in the stomach and to slow down stomach emptying, which may help you lose weight.
Sedation: Medication used to make you feel sleepy and less likely to feel pain during a medical test or procedure.
Side Effect: Something bad or harmful that can happen as a result of a medical treatment that may or may not be expected.

What are IGBs?

The Spatz3 Adjustable Balloon has been implanted worldwide since 2012, with over 76,000 balloons implanted outside of the US as of March 2021 (based on Spatz FGIA sales data). The Spatz3 Adjustable Balloon is placed in your stomach with an out-patient endoscopy procedure without surgery (will be explained later). It is believed that IGBs help you lose weight by:

- taking up space in the stomach; and
- interfering with stomach emptying. It takes a lot longer for food to leave the stomach and enter the intestines, so that food remains in your stomach longer.

The combination of diet and exercise are necessary for successful weight loss with the Spatz3 Adjustable Balloon.

What is the *Spatz3 Adjustable Balloon*?

The Spatz3 Adjustable Balloon is a silicone (rubber like) balloon filled with salt water (saline) that has an attached tube that allows the balloon volume to be changed when necessary. It can stay in your stomach for up to eight months.

Doctors who use the Spatz3 Adjustable Balloon can customize the balloon size to their patient's needs during the balloon implantation period. There are times when the balloon needs to be made smaller and times when the balloon needs to be made larger.

Who Can Get the Spatz3 Adjustable Balloon

You are a candidate for the Spatz3 Adjustable Balloon if you have a 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 and are 22 years or older. You must be willing to follow a 14-month program. The program begins with the placement of the Spatz3 Balloon in your stomach for up to eight months. The program includes a healthy diet and exercise program during the time that you have the balloon and for six months after the balloon is removed.

Who cannot have the Spatz3 Adjustable Balloon Procedure (Contraindications)

There are several conditions that prevent a person from having a Spatz3 Adjustable Balloon:

- You have had prior surgeries or condition that may have led to a narrowing or blockage of your gastrointestinal tract. If your balloon deflates and passes into your intestines, it will cause a blockage also known as an obstruction and must be surgically removed. This bowel obstruction can lead to serious injury and even death.
- You have had previous surgery on the esophagus, stomach or duodenum. That includes both bariatric (weight-loss) surgery and non-bariatric surgery at any time in your life, including the first weeks of life.
- You have a history of 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 your bowel system.
- You have potential for upper gastrointestinal bleeding conditions such as esophageal or gastric varices (veins in your stomach that bleed), congenital or acquired intestinal telangiectasis (small, dilated blood vessels), or other congenital anomalies of the gastrointestinal tract such as atresias or stenoses.
- You have a gastric mass.
- You have a hiatal hernia > 2cm or severe or intractable gastro-esophageal reflux symptoms or if you have acid reflux symptoms to any degree that require more than one medication for symptom control.
- You have a structural abnormality in the esophagus or pharynx such as a stricture or diverticulum (an abnormal sac or pouch) that could impede passage of the balloon alongside the endoscope.
- You have achalasia or any other severe esophageal motility disorder that may pose a safety risk during the removal of the device.
- You have severe coagulopathy (clotting factors become more active than usual, resulting in inappropriate blood clot formation).
- You have insulin-dependent diabetes (either Type 1 or Type 2) or a significant likelihood of requiring insulin treatment in the following 12 months.
- You have any serious health condition unrelated to your weight that would increase the risk of endoscopy.
- You have chronic abdominal pain.
- You have motility disorders of the gastrointestinal tract such as gross esophageal motility disorders, gastroparesis (stomach emptying disorder) or intractable constipation.
- You have hepatic insufficiency or cirrhosis (degenerative disease of the liver resulting in scarring and liver failure)
- You have 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.
- You have alcoholism or drug addiction
- You are receiving daily prescribed treatment with aspirin > 100 mg, anti-inflammatory agents, anticoagulants or other gastric irritants. This includes blood thinner medications such as Coumadin, Plavix and others or anti-inflammatory medications (prescription and non-prescription such as Motrin, Ibuprofen, Alleve, Naprosyn, and many more)

- You are unable or unwilling to take prescribed proton pump inhibitor medication for the duration of the device implant. Not taking these medications increases the possibility of gastric irritations and ulcers.
- You are known to have, or suspected to have, an allergic reaction to materials contained in the system: Silicone rubber, White RAL 9010 colorant, Polypropylene, Carbon black colorant, Parylene C, SS316, Nylon type 6, FD&C #2 Blue colorant, ABS, Colorant 3 03244 Bianco, Cyanoacrylate, silicone primer MED-160, PVC, HDPE, Polycarbonate, Colorant -CC 12390 UNI WHITE.
- You have BOTH - 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.
- You are pregnant or breast-feeding.
- You have severe cardiopulmonary disease or other serious organic disease which might include known history of coronary artery disease, myocardial infarction (heart attack) within the past 6 months, poorly controlled hypertension, or required use of NSAIDs
- You have an untreated Helicobacter pylori infection. This is a bacterial infection that may or may not cause symptoms such as abdominal pain or nausea or difficulty eating. It can be treated successfully with medication. Having this infection increases the possibility of gastric irritations and ulcers.
- You are taking medications on specified hourly intervals that may be affected by changes to gastric emptying, such as anti-seizure or anti-arrhythmic medications
- You are taking corticosteroids, immunosuppressants, or narcotics
- You have symptomatic congestive heart failure, cardiac arrhythmia or unstable coronary artery disease.
- You have a pre-existing respiratory disease such as chronic obstructive pulmonary disease (COPD) or pneumonia
- You have a pre-existing cancer undergoing chemotherapy or radiation therapy.
- You have been diagnosed with an autoimmune connective tissue disorder (e.g. lupus, erythematous, scleroderma) or are immunocompromised.
- Your life expectancy is less than 1 year or you have severe renal, hepatic, pulmonary or cardiac condition.
- You have been diagnosed with genetic or hormonal cause for obesity such as Prader Willi syndrome or untreated hypothyroidism
- You have an eating disorder including night eating syndrome (NES), bulimia, binge eating disorder, or compulsive overeating. The balloons may not help you lose weight if you have these eating disorders or these habits.
- You have an untreated endocrine disorder affecting your weight
- You already have an intragastric balloon

Things you must do to avoid serious harm (Warnings)

You should be aware that the success of the Spatz3 Adjustable Balloon treatment is dependent on clinic support and your cooperation. The clinic support should include a dietician/nutritionist who will guide you through the different phases of the treatment. Visits at least monthly with phone or digital communication in-between visits are necessary to ensure your safety. This support guides you in choices

and quantities of food as well as understanding symptoms from the balloon. The key to balloon treatment success is understanding that signs such as burps or fullness are a warning that a change needs to be made in food choices or quantities. If ignored, these symptoms may increase in severity. You need to cooperate and communicate with the clinic staff and return for frequent visits and most importantly, report any change in symptoms promptly.

WARNING: Alert all your health care providers that you have the balloon and show them the Patient ID Card. This is to help your doctor treat you correctly.

WARNING: Return after eight months to have your balloon removed. Keeping your balloon in longer than eight months increases the risk of Balloon deflation and intestinal obstruction which could lead to surgery or death.

WARNING: The following are symptoms that need to be reported to your doctor:

i. Feeling very tired, stomach hurts, can't remember things, have trouble sleeping, or are constipated. These may be signs of a problem with the balloon.
ii. Feeling intense abdominal pain, or a swollen stomach (with or without discomfort), difficulty breathing, persistent and untreatable nausea and/or vomiting. These could indicate there may be an issue with the balloon.
iii. Unable to drink fluids, feeling weakness, not urinating as much as usual – these are signs of dehydration.
iv. Feeling severe persistent stomach pain / back pain combined with nausea or vomiting. These may be signs that the stomach is not emptying correctly or that there is an irritation of the pancreas.
v. Chest pain, painful swallowing, or painful breathing after placement of the balloon or after endoscopy. These may be signs of a tear or hole in the esophagus.
vi. Severe, steady abdominal pain which makes it difficult to take a deep breath or move around. These may be signs of stomach perforation.

WARNING: Check your urine every day to be sure it is not blue/green in color. That would be a sign of Balloon deflation which could lead to intestinal blockage surgery or death.

WARNING: Call your doctor immediately if you have a sudden loss of feeling of stomach fullness, or if you start experiencing a new stomach pain that is different from the stomach pains that you felt when the balloon was put in, or if the pain does not go away. If you are hungrier between meals or you are starting to regain weight, these may be signs that your balloon has deflated, and this must be relayed to your doctor. If you do not, it is possible that your balloon may have deflated and moved from your stomach into your intestines and caused a blockage, also known as an obstruction, and must be surgically taken out. This bowel obstruction can lead to serious injury and even death.

WARNING: A deflated balloon may be vomited or may pass in the stool.

WARNING: Take acid blocking medicines daily as prescribed by your doctor, such as Prilosec and Nexium, while the Spatz3 Adjustable Balloon is in your stomach. If you do not take this medicine daily, there is a higher risk of developing a stomach ulcer and perforation of your stomach, balloon deflation and possible bowel obstruction.

WARNING: Your doctor will instruct you to take Probiotic medications daily. These are good bacteria that will help your stomach in the event that bad bacteria start growing in your stomach – it is believed that the use of probiotic can prevent bad bacteria from causing diarrhea.

WARNING: If you are taking a serotonin drug, such as Prozac or Lexapro and many similar medications that are commonly used for depression or anxiety, and other over-the-counter drugs, there is a possibility of developing a serious medical conditions called “serotonin syndrome” if your balloon ruptures and methylene blue is released into the stomach. If you develop symptoms of confusion, headache, nausea and vomiting, very fast heart rate, or severe sweating you need to go to an emergency room and notify your doctor immediately. All medications, prescribed and over the counter, must be reviewed with your doctor.

WARNING: DO NOT take any stomach irritating medicines like non-steroidal anti-inflammatory drugs (NSAIDs) or greater than 100 mg daily of Aspirin while the balloon is in your stomach. Some examples of NSAIDs are Motrin or Advil. Please read the warnings on any medicines that you might take to see if they can hurt your stomach. You might get ulcers or bleeding if you take these kinds of medications while the balloon is in your stomach.

CAUTION: DO NOT have the balloon placed if you have severe coronary artery (blood vessels that supply the heart with blood) disease. The effects of this condition with use of the Spatz3 Adjustable Balloon are not known.

CAUTION: DO NOT have the balloon placed if you have uncontrolled hypothyroidism, Cushing's disease or syndrome, end stage renal disease or requiring hemodialysis within the past 6 months, or uncontrolled hypertension. The effects of these conditions with use of the Spatz3 Adjustable Balloon are not known.

CAUTION: DO NOT have the balloon placed if you have severe, unstable/uncontrolled medical conditions of major organ systems. The effects of these conditions with use of the Spatz3 Adjustable Balloon are not known.

Risks of the Spatz3 Adjustable Balloon Procedure

Endoscopy and Sedation Risks

The Spatz3 Adjustable Balloon is inserted into your mouth after you receive sedative medication through your vein. An endoscope is passed down your throat with your balloon and once it reaches the stomach, the balloon is inflated and the endoscope is removed. Endoscopy is a very commonly performed procedure that is very safe but there are risks. The most common risks of endoscopy include bleeding, infection, tearing of the esophagus or stomach, which could lead to a hole forming through your esophagus or stomach and passage of stomach contents into the lungs. These risks are rare and have been reported in 3 to 5 of every 10,000 endoscopies. In rare circumstances the endoscopy can cause a broken tooth from the mouth guard.

Sedation during the endoscopy procedure carries risks which are also rare, occurring in less than one in every 10,000 procedures. The most common side effects include slowing of your pulse or breathing rate which can be treated by your doctor using extra oxygen or medication to reverse the effects of the sedation. Patients with chronic illnesses of the heart, kidney, liver or other chronic illnesses are at higher risk for these side effects. In order to reduce risk, it is vital that you follow your doctor's dietary instructions prior to the procedures.

Risks During the 8 Month Spatz3 Adjustable Balloon Implantation

Patients implanted with the Spatz3 Adjustable Balloon frequently complain about nausea, vomiting, abdominal pain, a feeling of abdominal heaviness, acid reflux, constipation and diarrhea. Dehydration, dizziness, lightheadedness and falling episodes can occur. These may stop on their own, or you may need medicine. If the symptoms do not improve with medicine, your doctor can also make the balloon smaller. The balloon treatment may not be effective and may yield little or no weight loss.

Hair loss as a consequence of significant dieting can occur. Development of gallstones as a result of weight loss can occur. Occasionally, patients complain of back pain.

The fluid in your balloon could become infected and if the fluid leaks rapidly into your intestines, it could cause infection, fever, cramps and diarrhea.

The balloon can block the outlet of your stomach or may cause significant delay of stomach emptying, which could cause distention, nausea, vomiting, dehydration and weakness. Any of these could require an endoscopy procedure to fix the symptoms.

Injury to the digestive tract could occur 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.

During filling of the balloon, the balloon could be inadvertently pulled back from the stomach and into the esophagus, which could cause esophageal obstruction. This rare episode could require endoscopy procedure correction, balloon removal or surgical intervention.

The balloon has been shown to delay stomach emptying into the intestine, however, rarely it may cause extreme delay in stomach emptying which could lead to food accumulation, rotting of food and infection within the stomach. This infected food could then enter the small intestine causing diarrhea – this is called bacterial overgrowth- and is treated with antibiotics and liquid diet.

There have been cases of spontaneous hyperinflation of the balloon (Bacterial growth in the fluid which fills the balloon with gas). Rapid release of this fluid into the intestine could cause infection, fever, cramps and diarrhea and may require removing the balloon.

Pancreatitis (inflammation of the pancreas organ) can occur, causing pain, nausea and vomiting. This may require removing the balloon.

More serious side effects are rare but include vomiting blood or passing blood in your stool, aspiration pneumonia, stomach or esophagus perforation (making a hole in the esophagus or stomach) that requires emergency surgery, or a deflated balloon that leads to bowel obstruction which requires emergency surgery. A deflated balloon can be passed harmlessly in the bowel movement or remain in the stomach requiring removal by endoscopy. A deflated balloon can also be vomited, which could result in laryngospasm (spasm of the throat with difficulty breathing), hypoxia (low oxygen level), esophageal injury, and pulmonary aspiration (stomach contents entering lung which causes pneumonia). Any of these can result in loss of work, hospitalization or death.

US Clinical Study Results

The US clinical study was performed in 7 clinical centers in the United States. The study was a randomized controlled study which means that patients were enrolled and then were assigned by chance (like flipping a coin) to either receive the balloon with a diet and exercise program or receive the same diet and exercise program alone. The clinical study patients were all at least 22 years old with a BMI between 30-40 kg/m^2. Patients were not allowed to be in the clinical study if they met one or more exclusion criteria.

The Spatz3 Adjustable Balloons were put in and taken out in the clinical study and were adjusted (up or down) in the same way that your balloon will be put in, taken out, and adjusted. All clinical study patients had monthly follow up visits for 8 months where the doctor's staff collected information on weight loss and side effects. The patients also were instructed to follow a 1000-1200 kcal/day-deficit diet during their participation in the study.

There were 187 patients implanted with the Spatz3 Adjustable Balloon for 8 months and 101 served as control patients without the balloon. 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 balloon 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.

Spatz3 Adjustable Balloon Side Effects After Implantation

Serious Side Effects in the US Clinical Study

Serious side effects are health problems which:
1. May lead to hospitalization;
2. Result in an illness or injury which puts you at risk for death;
3. Cause long lasting injury to the body;
4. Need quick medical treatment or surgery to prevent bodily injury.

There were no side effects that led to surgery or death during the US Clinical Study. Ten out of 187 (5.3%) study subjects who received the balloon experienced 29 serious side effects. Of the 29 serious side effects, 24 serious side effects occurred in seven subjects that were related directly to the Spatz3 Adjustable Balloon. Therefore, the device-related serious side effect rate is 3.7% (7/187). There was one procedure related serious side effect. All serious side effects resolved without any long term problems afterwards. Out of the 7 subjects with serious side effects, 4 subjects had an early balloon removal. These 4 subjects did not have a balloon down adjustment as they had mucosal pathology (abnormal endoscopies) that were associated with their symptoms which supported the need for device removal.

Table 1 lists the different types of serious side effects that 7 patients experienced during the US Clinical Study. Each patient had 2 or more of the following symptoms listed in the table.

Table 1: Patients with Serious Side Effects in the US Clinical Study

Serious Side Effect	Number of subjects with these side effects* (%)	Harm or Potential Harm	# of subjects with this side effect who had their balloon removed early
Nausea	6 out of 187 (3.2%)	Feel Like vomiting	2 out of 6
Vomiting	5 out of 187 (2.7%)	Dehydration	2 out of 5

Serious Side Effect	Number of subjects with these side effects* (%)	Harm or Potential Harm	# of subjects with this side effect who had their balloon removed early
Abdominal pain	4 out of 187 (2.1%)	Pain, discomfort, or rigidity; reduced well-being and need for further evaluation or treatment, including surgery.	2 out of 4
Dehydration	3 out of 187 (1.6%)	Loss of fluids in your body. Low blood volume (shock) and reduced kidney function.	1 out of 3
Diarrhea	2 out of 187 (1.1%)	Dehydration. Abnormal changes in the body's minerals (electrolytes) or chemical imbalance.	0 out of 2
Gastroesophageal reflux disease	1 out of 187 (0.5%)	Heartburn or burning sensation starting from lower chest and may rise up to the throat. Injury to the esophagus.	1 out of 1
Weakness*	1 out of 187 (0.5%)	Unable to function as usual	1 out of 1
Hypokalemia (Low Potassium level in blood)	1 out of 187 (0.5%)	Muscle cramping and abnormal heart rhythms.	0 out of 1
Esophageal Mucosal Tear	1 out of 187 (0.5%)	This could cause a hole in the esophagus to form which requires surgery to repair and could lead to death	1 out of 1

*Weakness resulted from the following AEs: Nausea, Vomiting, Dehydration, Abdominal pain. This may also be referred to as "failure to thrive".

One subject in the US clinical study on the day of planned extraction (at 8 months) was noted to have a deflated balloon in the stomach (1 out of 187 (0.5%)) – this was caused by fungal infection on the surface of the balloon. The deflated balloon was removed in the usual manner on that day. The Spatz3 Adjustable Balloon deflation caused by fungal infection of the balloon surface has been reported from use outside of the US in 3 out of 1,000 patients and balloon deflation with migration into the bowel in 7 out of 100,000 patients.

In the US clinical study, some known serious side effects related to intragastric balloons in general were not observed. These potentially serious side effects are listed in Table 2 below. How often the serious side effects may occur in the US are unknown based on the US clinical study. However, there is information based on use of the Spatz3 Adjustable Balloon in the rest of the world which may be useful in understanding how likely it is that these events may occur in the US.

Table 2: Possible Serious Side Effects which did not occur in the US clinical study

Possible Serious Side Effect	**Harm (Possible Serious Adverse Event)**	**Occurrence in the World**
Hole in the wall of the stomach	The balloon causes a hole in the stomach which requires surgery to repair and could lead to death	2.5 out of 10,000 patients
Life threatening allergic reaction (anaphylaxis)	You will need medications and/or need to have a tube placed in your airway to help you breathe during the procedure to take out the balloon.	1 out of 100,000 patients
Heart attack (myocardial infarction)	Your heart muscle becomes temporarily or permanently damaged.	unknown
Blood circulation stops (cardiac arrest)	You need to have your heart restarted with medications or an electrical shock through your chest.	unknown
Hole in the wall of the esophagus	The balloon is inflated in the esophagus instead of the stomach during the placement of the balloon causing a tear or hole in the esophagus and possibly death.	4 out of 100,000 patients
Airway obstruction (respiratory distress)	Total blockage of the airway by the balloon when it is being taken out.	unknown

Possible Serious Side Effect	Harm (Possible Serious Adverse Event)	Occurrence in the World
Compression of Pancreas	Inflammation of pancreas that can cause nausea, vomiting, pain, dehydration	unknown
Gastric outlet obstruction	The balloon or valve can block (partial or full) the pyloric which can produce a mechanical impediment to gastric emptying	3 out of 100,000 patients
Gastric atony	Inability of the stomach to contract normally, causing a delay in the movement of food out of the stomach	Unknown
Bleeding	Injury of the GI track tissue during balloon treatment	1 out of 100,000 patients
Spontaneous Hyperinflation	Enlargement of the balloon by gas or fluid by itself while it is in the patient's stomach. This can cause nausea, vomiting, pain, dehydration, ulcer and stomach perforation. The balloon will need to be removed early.	4 out of 10,000 patients
Deflated balloon with intestinal obstruction	A deflated balloon can pass into the intestines and get stuck causing a blockage. This requires advanced radiology procedure or surgery to remove the balloon. If untreated it can lead to death	3 out of 10,000 patients
Deflated balloon caused by bond failure	The balloon can be deflated due to parts bond failure. * this cause was eliminated followed by device improvement	8 out of 1,000 patients
Deflated balloon with unknown cause	The balloon can be deflated while located within the stomach and should be removed by endoscopy.	5 out of 1,000 patients

Possible Serious Side Effect	Harm (Possible Serious Adverse Event)	Occurrence in the World
Deflation of balloon that is passed in stool	A deflated balloon passing through the gastrointestinal tract and exit in the bowel movement or could cause intestinal obstruction needing an advanced radiology procedure or surgery to remove and could potentially cause death.	3 out of 1,000 patients
Deflated balloon caused by cap failure	The balloon can be deflated due to cap leak which is caused by not closing the cap tightly.	6 out of 10,000 patients.
Deflated balloon caused by holes or balloon burst	The balloon can be deflated due to micro holes or balloon burst during the treatment	9 out of 10,000 patients.
Deflation of balloon that is vomited	A vomited balloon could potentially cause spasm of the throat with difficulty breathing, low oxygen level, esophageal injury, and/or stomach contents entering lung which causes pneumonia	2 out of 10,000 patients.
Death*		9 out of 100,000 patients

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

Side Effects

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 balloon subjects (183/187, 98%) experienced gastrointestinal side effects, with nausea, dyspepsia (indigestion) and vomiting being the most frequent (90% (169/187), 74% (137/187), and 72% (134/187) of subjects, respectively). Ten (10) of the 187 balloon subjects (5.3%) required intravenous fluid infusion or intramuscular injections of medication for severe nausea and vomiting. Other than gastrointestinal-related side effects: headache (44/187, 24%), hiccups (63/187, 34%), dizziness (40/187 21%), and dehydration (38/187, 20%) were the most frequent.

Table 3 - All Side Effects in the US Clinical Study of 187 Balloon Patients

Side Effect	Number (%) of patients who had side effect	Harm
Nausea	169 (90%)	Uneasy feeling in the stomach or feeling like you need to throw up
Dyspepsia	136 (73%)	Stomach feels full of gas, burping, pain or discomfort in the stomach or belly
Vomiting	134 (72%)	Possible dehydration/Chemical imbalance
Burping/Belching (Eructation)	121 (65%)	Could be embarrassing in public
Abdominal pain	113 (60%)	Unpleasant or painful feeling in the stomach that can prevent you from doing your normal activities. Reduced well-being and need for further evaluation or treatment, including surgery.
Constipation	95 (51%)	Abdominal pain or distention
Diarrhea	72 (39%)	Possible dehydration/Chemical imbalance
Breath odor	61 (33%)	Foul smelling which could be embarrassing in public
Abdominal rigidity	38 (20%)	A stiff abdomen caused by pain
Abdominal distension	29 (16%)	Abdomen is larger due to gas and fluid accumulation in stomach
Gastroesophageal reflux disease	18 (9.6%)	Heartburn
Esophagitis	13 (7.0%)	Inflammation of the esophagus due to acid going up from the stomach into the esophagus which causes pain and difficulty eating
Flatulence	8 (4.3%)	Gassiness
Regurgitation	6 (3.2%)	Stomach contents come back up to throat which can cause heartburn
Gastritis	5 (2.7%)	Irritation in the stomach lining which can cause pain and food intolerance and can progress to an ulcer if untreated
Esophageal mucosal tear	4 (2.1%)	Superficial tear of the esophagus caused during the procedure that can cause bleeding
Gastritis erosive	3 (1.6%)	Irritation in the stomach lining with superficial sores which can cause pain and food intolerance and can progress to an ulcer if untreated
Dry mouth	4 (2.1%)	Dry mouth caused by decreased oral intake or vomiting

Gastric ulcer	4 (2.1%)	Pain that is caused by a sore inside your stomach, which can potentially cause a hole in the stomach and bleeding
Retching	2 (1.1%)	Scratchy, painful throat/Possible minor bleeding
Hematemesis (bloody vomit)	2 (1.1%)	Drop in blood count/Weakness
Esophageal bleeding	2 (1.1%)	Drop in blood count/Weakness
Hematochezia	1 (0.5%)	Passing blood in the bowel movement
Hyperchlorhydria	2 (1.1%)	Acid increased in the stomach which can cause pain
Salivary hypersecretion	1 (0.5%)	A lot of saliva in the throat
Proctalgia	1 (0.5%)	Pain due to a spasm of the pelvic floor muscles, the muscles of the anal sphincter, or the muscles of the rectum
Oral disorder	1 (0.5%)	Mouth or throat discomfort from the procedure or acid reflux that may cause eating or swallowing discomfort
Headache	44 (24%)	Head hurts such that it is hard to do your normal daily activities. In the case of a migraine you could have nausea and dizziness.
Dizziness	40 (21%)	Lightheadedness which could lead to falling episodes
Migraine	1 (0.5%)	Head hurts such that it is hard to do your normal daily activities. In the case of a migraine you could have nausea and dizziness.
Syncope	1 (0.5%)	Weakness/Difficulty performing tasks Fainting
Tremor	1 (0.5%)	Hand shaking
Change of food taste (Dysgeusia)	1 (0.5%)	Difficulty with eating
Hiccups	63 (34%)	Discomfort for a short time. Difficulty breathing
Oropharyngeal pain	6 (3.2%)	Throat pain
Cough	2 (1.1%)	Cough
Dyspnea	2 (1.1%)	Shortness of breath
Throat irritation	2 (1.1%)	Soreness in throat
Coughing Blood (Hemoptysis)	1 (0.5%)	Coughing up blood in the sputum
Dry throat	1 (0.5%)	Dry throat can be uncomfortable to swallow
Aspiration	1 (0.5%)	Stomach contents go up the esophagus and into lungs – can cause coughing and pneumonia
Dehydration (excessive loss of body fluids)	38 (20%)	Weakness, unable to perform usual activities
Concentrated urine	26 (14%)	A sign of dehydration

Decreased appetite	3 (1.6%)	Less food intake
Low potassium (Hypokalemia)	1 (0.5%)	If untreated can cause muscle cramps and heart rhythm abnormalities
Failure to thrive	1 (0.5%)	Weakness and inability to function up to par
Low Calcium (Hypocalcemia)	1 (0.5%)	If untreated can cause twitches in the short term, and bone issues in the long run
Fatigue	20 (11%)	Weakness and sleepiness
Chest pain	6 (3.2%)	Pain in the chest
Asthenia (loss of strength)	4 (2.1%)	Unable to function as usual
Pyrexia	2 (1.1%)	Elevated temperature (fever)
Chest discomfort	4 (2.1%)	Discomfort in the chest due to balloon fullness in the stomach
Sensation of foreign body	4 (2.1%)	Sensation of something sitting in your stomach
Hunger	1 (0.5%)	Hunger
Malaise	1 (0.5%)	weakness and inability to function up to par
Muscle spasms	9 (4.8%)	Spasms or pain in muscles usually due to dehydration and chemical imbalance
Back pain	5 (2.7%)	Back pain
Musculoskeletal chest pain	1 (0.5%)	Discomfort in the chest and in the muscles between the ribs
Erythema	1 (0.5%)	Redness in stomach lining which can cause difficulty eating
Skin exfoliation	1 (0.5%)	Skin reaction with peeling of skin
Anxiety	2 (1.1%)	anxious
Nephrolithiasis	1 (0.5%)	Kidney stone
Blood pressure increased	1 (0.5%)	Headache/Blurred vision/Difficulty concentrating/Stomach pain
Vision blurred	1 (0.5%)	Blurred vision usually due to dehydration and or medications
Dry eye	1 (0.5%)	Dry eye
Visual impairment	1 (0.5%)	Impairment in sight usually due to dehydration and or medications
Iron deficiency anemia	1 (0.5%)	Low blood count due to low iron level- can cause weakness
Deflated balloon caused by fungus on balloon surface	1 (0.5%)	A deflated balloon can remain in the stomach for a period of time where it can be removed safely with endoscopy or it can pass through the intestines naturally, or it can be vomited or it can obstruct the intestine and cause a bowel obstruction requiring surgery.

If you have nausea and vomiting, it can be treated with anti-nausea medications. If your symptoms are more severe, fluids may be given to you through a needle in your vein. If you have abdominal pain, your doctor will prescribe pain medications as needed to control the pain. If you cannot tolerate your symptoms, you can always choose to have the balloon taken out before 8 months. In the US Clinical Study, 50 out of the 187 subjects with a balloon (50/187, 27%) asked to have their balloon taken out before the 8 months had passed (this is about 1 out of every 4 patients). Twenty-eight of the 50 subjects who requested a balloon removal due to side effects had the volume of the balloon reduced with an endoscopic procedure; whereas, the other 29 subjects had the balloon removed. Of the 28 subjects who had downward adjustments, 21 completed the 8-month balloon implantation procedure, but 7 had the balloon removed due to their side effects.

Spatz3 Adjustable Balloon Fluid Removal to Reduce Side Effects

The Spatz3 Adjustable Balloon offers the ability to remove fluid from the balloon to decrease its size in order to reduce side effects. There were 28 patients in the US Clinical Study who had down adjustments (remove liquid from the balloon) to reduce side effects. Of these 28 subjects, 21 were able to complete the 8-month balloon implantation period, and two avoided immediate removal and continued at least 100 more days prior to removal.

Weight Loss Benefits of the Spatz3 Adjustable Balloon

The Spatz3 Adjustable Balloon was shown to help patients lose weight. Patients who received the Spatz3 Adjustable Balloon along with a diet and exercise program lost more weight than patients who did the diet and exercise program alone.

The patients who received the Spatz3 Adjustable Balloon lost on average 15% of their total body weight, while patients who received only diet and exercise lost on average 3.3% of their total body weight. At six months after the balloon was removed, 74% of the patients who returned to have their weight measured had kept at least 40% of the weight they lost off.

Good things about the Spatz3 Adjustable Balloon

The procedure is done as an out-patient with endoscopy under sedation (you are given medications through the intravenous line so that you are comfortable). There is a 1 hour recovery time- and then you go home. It does not require surgery. The balloon can be kept in for up to 8 months which gives you time to improve your eating habits, while exercising, and all under the support of your doctor and your doctor's staff. You can learn to approach food differently with the Spatz3 Adjustable Balloon lifestyle program, so that after the balloon is removed you can continue with a healthy lifestyle.

As you can imagine, getting the right size balloon is not simple. Balloon size cannot be determined by the size of your stomach. The correct balloon size depends on how sensitive your stomach is – and that cannot be determined prior to or during the endoscopy procedure. If you have difficulty tolerating the balloon, that's where the Spatz3 Adjustable Balloon can help because the balloon can be made smaller with an additional endoscopic procedure.

How to decide about the Spatz3 Adjustable Balloon

The Spatz3 Adjustable Balloon treatment might be right for you if you are an adult with a body mass index (BMI) from 35 to 40 kg/m^2 or a BMI of 30-34.9 kg/m^2 with a major obesity related medical issue and you have failed to lose weight with diet and exercise alone. During your treatment with the Spatz3 Adjustable Balloon, you must continue to follow your doctor recommended diet and exercise program in order to achieve the most weight loss.
It is important for you to look at alternative weight loss treatment programs. The Spatz3 Adjustable Balloon is not the only treatment available. There are other intragastric balloons, medications, and for those who qualify, there are surgical procedures. This should be discussed with your doctor so that you can choose the option that best fits your needs.

The table below can help you tell if your BMI is within the approved BMI numbers for the Spatz3 Adjustable Balloon Procedure. To use the table, find your height in the left-hand column. Then move across the top and find your weight (with clothes on but without shoes). The number in the box where your height and weight come together is your BMI. If your BMI is blue, your BMI is within the BMI numbers approved for the Spatz3 Adjustable Balloon Procedure. Your doctor can also help you to find out your BMI.

Height (in.) \ Weight (lbs.)	160	170	180	190	200	210	220	230	240	250	260	270	280	290	300	310	320	330
5'0"	31	33	35	37	39	41	43	45	47	49	51	53	55	57	59	61	63	65
5'1"	30	32	34	36	37	39	42	44	45	47	49	51	53	55	57	59	61	63
5'2"	29	31	33	34	36	38	40	42	44	46	48	50	51	53	55	57	59	61
5'3"	28	30	32	33	35	37	39	41	43	44	46	48	50	52	53	55	57	59
5'4"	27	29	31	32	34	36	38	40	41	43	45	46	48	50	52	53	55	57
5'5"	26	28	30	31	33	35	37	38	40	42	43	45	47	48	50	52	53	55
5'6"	25	27	29	30	32	34	36	37	39	40	42	44	45	47	49	50	52	53
5'7"	25	26	28	29	31	33	35	36	38	39	41	42	44	46	47	49	50	52
5'8"	24	25	27	28	30	32	34	35	37	38	40	41	43	44	46	47	49	50
5'9"	23	25	26	28	29	31	33	34	36	37	39	40	41	43	44	46	47	49
5'10"	23	24	25	27	28	30	32	33	35	36	37	39	40	42	43	45	46	47
5'11"	22	23	25	26	28	29	31	32	34	35	36	38	39	41	42	43	45	46
6'0"	21	23	24	25	27	28	30	31	33	34	35	37	38	39	41	42	44	45
6'1"	21	22	23	25	26	27	29	30	32	33	34	36	37	38	39	41	42	44
6'2"	20	21	23	24	25	27	28	30	31	32	33	35	36	37	39	40	41	42
6'3"	19	21	22	23	24	26	28	29	30	31	33	34	35	36	38	39	40	41
6'4"	19	20	21	23	24	26	27	28	29	31	32	33	34	35	37	38	39	40

What are the first steps In the Spatz3 Adjustable Balloon Procedure

Your doctor will review your medical history and perform a physical exam to help determine if the Spatz3 Adjustable Balloon is a good choice for you. It is important that you give a detailed account of your past medical history, surgical history, medication history to your doctor so that they can determine if the Spatz3 Adjustable Balloon is a good option for you. Surgical history is vitally important because there are certain surgeries that you may have undergone that would disqualify you as an appropriate candidate - even if they occurred when you were an infant. Your doctor will explain to you how intragastric balloons work, and how the Spatz3 Adjustable Balloon will help you achieve a healthier lifestyle. During this discussion you will be told about the risks and benefits of the treatment. You will then receive instructions and prescription medications from your doctor.

A dietician or nutritionist will meet with you and take a full dietary history to help better understand your nutritional needs.

What happens during the Spatz3 Adjustable Balloon procedures?

Your doctor will set a date for you to have the balloon placed in your stomach.

You will have been given prescriptions to purchase medications to help with nausea, vomiting and stomach pain. Make sure that you fill these prescriptions prior to the day of the procedure. It is important that you take these medicines as prescribed. However, it is important to understand that even if you take these medicines you will most likely have some or all of the symptoms lasting 3 to 4 days and occasionally up to 1 week.

Warning: you may not eat or drink anything for 12 hours before your scheduled procedure. Food or liquid in your stomach could enter your lungs and cause harm.

On the day of your Spatz3 Adjustable Balloon procedure:

1. Please notify your doctor if there have been any changes to your health, eating habits or medications since your last visit. If you are a woman who could get pregnant, you will need to have a pregnancy test.

2. The balloon is placed in your stomach using an endoscope-a flexible tube with a light at the end. This is done under sedation which means that you will be sleeping during the procedure. The balloon will be filled with salt water (saline) and a blue dye. The blue dye is placed in the balloon so that if your balloon breaks and the fluid leaks out of the balloon, your urine should turn blue. After the procedure you will be watched in the recovery unit for approximately one hour by a doctor or nurse. When you are awake and can swallow and walk under your own power, you will be sent home. You will need to come with a person that can drive you home.

3. You may not drive, use machinery or power tools, or make any important decisions for 24 hours after the procedure. The sedation that you receive will affect your judgment and thinking even if you do not feel it.

4. If you develop pain or redness at the area on your arm where a needle was placed for your IV fluids, you need to call your doctor. If this is not taken care of properly you could develop a clot or swelling in the vein which would cause pain.

5. If you do not urinate (pee) for 12 hours after going home from the procedure, that would mean that you are not getting enough fluids. You need to alert your doctor if this occurs.

Living with the Spatz3 Adjustable Balloon

Week 1
The following is an estimation - every patient is different, so you should expect the timing and type of your symptoms to vary, and your Dietician may guide you differently than what is shown below.

First 24 hours:
- Try to drink clear liquids such as broth, gelatin, ice chips, water, apple juice, coffee, or tea. Warm liquids may sometimes be better tolerated then cold liquids. Carbonated drinks such as soda or pop may cause gas and bloating and should be avoided in the first few weeks.
- You should try to drink at least 4 to 6 cups of liquid per day. That may not be so easy to achieve. You should start by taking small sips and building up slowly over time. Never drink more than a quarter of a cup at a time.
- It is best to sit upright for 2 to 3 hours after drinking. Use a recliner chair rather than lying flat when resting.
- Do not drink more than one cup of coffee or caffeine containing drinks per day. Caffeine can cause cramps or diarrhea which could lead to dehydration.
- It is possible that you may not be able to drink more than a cup of liquid on your first day. That is OK as long as your fluid intake increases the following day.

First 3 days:
Most people are quite weak for 3-7 days because they are drinking and eating very little. It is important to rest in the first three or four days. Light activities such as walking are allowed.

First week:
As you begin to eat more you may develop nausea and vomiting. If this happens you need to cut back and return to liquids and take medicines as directed by your doctor.

Caution: You may become dehydrated which could lead to lightheadedness, dizziness and a risk of falling episodes.

Each person will advance their diet carefully according to their symptoms, and with the advice of their nutritionist and doctor.

Week 2:
At the beginning of week 2 you will advance your diet according to your nutritionist or doctor.

- Chewing your food slowly and thoroughly will help you achieve satiety. Start paying attention to how you feel after each meal. You need to stop eating when you feel full or have any discomfort. If you ignore those feelings and continue to eat, that may result in abdominal pain, nausea, vomiting or heartburn.
- Any worsening of symptoms or a return of symptoms that were present immediately after the balloon was implanted, should be discussed with your doctor.
- As you move forward, you will follow up with your nutritionist and doctor on a regular basis. You will learn how to understand what the balloon is signaling and how to respond to it. This is a process that you will learn as time goes on.

Who needs a balloon adjustment?

Balloon size can be adjusted – made smaller or larger- with an endoscopy procedure with sedation similar to the implantation procedure. Your stomach needs to be empty for the procedure. This is very important because if you do not follow this three-day diet, your stomach could be filled with food which could enter your lungs which could lead to aspiration pneumonia and death. Making sure that your stomach is empty will require a 3-day diet:

- 72 hours prior to the procedure: Soft food only, no meat or vegetables in any form.
- 48 hours prior to the procedure: Full liquids only.
- 24 hours prior to the procedure: Clear liquids only.
- 12 hours prior to the procedure: No food or liquids by mouth

As stated earlier, the first week is uncomfortable, however, the symptoms usually improve from day 4 to day 7. If you have difficulty tolerating the balloon, that's where the Spatz3 Adjustable Balloon can help you because the balloon can be made smaller with an endoscopic procedure. This way you may continue with the treatment.

If your doctor determines that the effects of the balloon are wearing off, your doctor may suggest adding additional liquid to the balloon to make it larger. This may help you to lose more weight and prevent weight regain.

When Do I Notify My Doctor?

You should promptly notify your doctor if any of the following occur while the balloon is in place:

- If you become pregnant while the device is in place. There is a risk that if the balloon were to rupture and the blue dye inside the balloon is released, the blue dye could cause birth defects. In laboratory testing, this blue dye caused damage to bacteria, animal cells, and human tissue; however, the effect of the release of the blue dye into your stomach after the balloon ruptures is unknown.
- If you cannot keep liquids down and cannot swallow or if you are nauseated or throwing up. This can lead to dehydration and possible kidney damage.
- If you begin to experience new or more severe pain or trouble breathing, cough and shortness of breath, coughing, spitting or throwing up blood, bloody or black stools.
- If you experience pain or redness at the site of IV injection.
- If you find that you're able to eat more and feel that the balloon is less effective. This may be a sign that your balloon has deflated. A deflated balloon may be removed from your stomach with an endoscopy procedure, or it may pass into your intestines and into your stool or block your intestines which could lead to surgery and death. A deflated balloon can also be vomited, which could result in laryngospasm (spasm of the throat with difficulty breathing), hypoxia (low oxygen level), esophageal injury, and pulmonary aspiration (stomach contents entering lung which causes pneumonia).
- If you are taking a serotonin drug such as Prozac or Lexapro and many similar medications, and other over-the-counter drugs there is a possibility of developing a serotonin syndrome if your balloon ruptures and the blue dye is released into the stomach. If you develop symptoms of confusion, headache, nausea and vomiting, rapid heart rate, or severe sweating you need to go to an emergency room and notify your doctor immediately. All medications, prescribed and over the counter, must be reviewed with your doctor.

After balloon removal, please call your doctor if you develop a fever or chills, nausea or vomiting, coughing, spitting or throwing up blood, bloody or black bowel movements, stomach pain, pain or redness at the site of IV injection, or no urination for 12 hours after going home from the clinic.

Spatz3 Adjustable Balloon Removal

You must have your Spatz3 Adjustable Balloon removed no later than eight months (240 days) after it is placed. The risk of balloon deflation increases if it is left in place longer than eight months. This can be dangerous because a deflated balloon can cause bowel obstruction or other problems that could lead to death.

Warning: The same 3-Day dietary restrictions that are used prior to adjustment procedures are also used prior to the balloon removal. This is very important because your stomach needs to be empty for this procedure so that it can be done safely. If you do not follow this three-day diet, your stomach could be filled with food which could move up your esophagus and into your lungs which could lead to aspiration pneumonia and death. Here again is the 3-day diet:

- 72 hours prior to the procedure: Soft food only, no meat or vegetables in any form.
- 48 hours prior to the procedure: Full liquids only.
- 24 hours prior to the procedure: Clear liquids only.
- 12 hours prior to the procedure: No food or liquids by mouth

The balloon removal procedure is similar to the implantation and adjustment procedures. You will be sedated so that you are sleeping during the procedure. The doctor will place the endoscope through your mouth and into your stomach, deflate the balloon, and remove it. You will go home approximately one hour after the procedure.

Instructions after balloon removal: Do not drive or use machinery or power tools or make any important decisions for 24 hours after the procedure. The sedation that you received during the procedure may impair your judgment without you knowing it. This could cause you to make mistakes or have accidents.

For the first week after the balloon is removed, your stomach will not be completely back to normal because the stomach muscles have been very lazy for the previous eight months and it takes time for them to go back to normal. That means that heavy foods such as raw vegetables, meats, salads will take longer to move from your stomach into the intestine. That could be very uncomfortable. It is recommended that you start with liquid diet and move on to soft foods over three or four days. Gradually increase to meats, chicken, salads and vegetables after four or five days.

Please call your doctor if you develop a fever or chills, nausea or vomiting, coughing, spitting or throwing up blood, bloody or black bowel movements, stomach pain, pain or redness at the site of IV injection, or no urination for 12 hours after going home from the clinic.

Life after Spatz3 Adjustable Balloon:

The lifestyle program that you received during your eight months with the Spatz3 Adjustable Balloon, explained that the symptoms that you received from your balloon such as burping, fullness, heaviness, gas pains and others were signs to remind you that there was an overload of food in your stomach. That, in turn, was there to remind you that you need to take responsibility for what you eat. Now that you no longer have a balloon, you need to internalize the lessons you learned- starting a new and healthy lifestyle. That includes, among other things, correct eating and exercise. Be sure to follow up with your doctor and nutritionist/ dietitian to help you maintain your weight loss.

Patient ID Card

You will receive a Spatz3 Adjustable Balloon ID card following your procedure. Please carry this Spatz3 ID card with you at all times. Notify your health care providers that you have a Spatz3 Adjustable Balloon. If you lose this card, please call your doctor’s office to receive a new card.

Questions/ Assistance:

Your doctor or clinic will provide you with 24hour telephone contact information for any questions, assistance or emergencies.

For any assistance please contact:
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