



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	4
What are IGBs	4
What is the Spatz3 Adjustable Balloon?	5
Who Can Get the Spatz3 Adjustable Balloon	5
Who cannot have the Spatz3 Adjustable Balloon Procedure (Contraindications)	5
Things you must do to avoid serious harm (Warnings)	7
Risks of the Spatz3 Adjustable Balloon Procedure	7
<i>Endoscopy and Sedation Risks</i>	7
<i>Possible complications During the 12 Month Spatz3 Adjustable Balloon Implantation</i>	8
Good things about the Spatz3 Adjustable Balloon	9
How to decide about the Spatz3 Adjustable Balloon	9
What are the first steps In the Spatz3 Adjustable Balloon Procedure	9
What happens during the Spatz3 Adjustable Balloon procedures?	10
Living with the Spatz3 Adjustable Balloon	10
Who needs a balloon adjustment?.....	11
When Do I Notify My Doctor?.....	11
Spatz3 Adjustable Balloon Removal	12
Life after Spatz3 Adjustable Balloon:	13
Patient ID Card	13
MR Conditional	13
Questions/ Assistance:	13

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.

A 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.

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;
- 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 12 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

- Pre-surgical temporary use for weight loss in morbidly obese patients (BMI 40 and above or a BMI of 35 with co-morbidities) prior to bariatric or other surgery, in order to reduce surgical risk.
- Temporary use for weight loss in overweight and obese patients (BMI > 27) 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.

Who cannot have the Spatz3 Adjustable Balloon Procedure (Contraindications)

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

- You are less than 18 years.
- You are pregnant or breast-feeding.
- 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 severe coagulopathy (clotting factors become more active than usual, resulting in inappropriate blood clot formation).
- 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 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 been diagnosed with an autoimmune connective tissue disorder (e.g. lupus, erythematous, scleroderma) or are immunocompromised.

- 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 any other medical condition which could increase the risk of elective endoscopy or weight loss.
- 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 clinically significant hiatal hernia, esophageal diverticulum (pouch that protrudes outward in a weak portion of the esophageal lining), stenoses, rings or webs that can cause device implantation above the diaphragm.
- 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 motility disorders of the gastrointestinal tract such as gross esophageal motility disorders, gastroparesis (stomach emptying disorder) or intractable constipation.
- You require continuous therapy with known ulcerogenic medication (e.g., aspirin, non-steroidal anti-inflammatory agents, COX-2 inhibitors), anti-coagulants or anti-platelet agents.
- You are unable or unwilling to participate in a medically supervised diet and behavior modification program with frequent follow up meetings.
- You are allergic to Silicone.

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 at 12 months to have your balloon removed. Keeping your balloon in longer than 12 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: 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: 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.

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.

Common adverse reaction to sedation or local anaesthetic may include: Abdominal cramps and discomfort from the air used to distend the stomach; Sore or irritated throat following the procedure; Aspiration of stomach contents into the lungs; Cardiac or respiratory arrest (these are extremely rare and are usually related to severe underlying medical problems); Digestive tract injury or perforation; Upper digestive tract bleeding.

Possible complications During the 12 Month Spatz3 Adjustable Balloon Implantation

The Balloon may be deflated during the treatment and should be replaced promptly. A deflated balloon can be passed harmlessly in

the bowel movement or remain in the stomach requiring removal by endoscopy, or a deflated balloon that leads to bowel obstruction which requires abdominal surgery and/or subsequent surgery. Death due to complications related to intestinal obstruction or surgery is possible.

The balloon treatment may not be effective and may yield little or no weight loss

The balloon placement may cause Injury to teeth, tissue in the oral cavity or throat and upper esophageal sphincter.

Temporary weight-loss treatments have been shown to have poor long-term success rates (weight-loss maintenance) in severely obese patients.

Adverse health consequences resulting from weight loss such as 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.

Patients implanted with the Spatz3 Adjustable Balloon frequently complain about nausea, vomiting, abdominal pain, a feeling of abdominal heaviness, Gastroesophageal 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 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 alleviate the symptoms.

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

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.

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.

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.

Catheter entrance into the duodenum causing anorexia, nausea, vomiting or abdominal pain. This is not uncommon and usually spontaneously resolves and is well tolerated, however, it could require endoscopy to pull the catheter back into the stomach.

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.

More serious side effects are rare but include stomach or esophagus perforation (making a hole in the esophagus or stomach) that requires emergency surgery. Any of these can result in loss of work, hospitalization or death.

NOTE: Any serious adverse incident that occurs in relation to the device should be reported to the manufacturer (www.Spatzmedical.com), in Australia, to the TGA (www.tga.gov.au) and in New Zealand, to Medsafe (medsafe.govt.nz).

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 12 months which gives you time to improve your eating habits, while exercising, and all under the support of your doctor and your allied health team. 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 (above 18 years) with a body mass index (BMI) above 27 and failed to achieve and maintain weight-loss with a supervised weight control program or a BMI 40 and above or a BMI of 35 with comorbidities intended for pre-surgical temporary use for weight loss in morbidly obese patients (prior to bariatric or other surgery, in order to reduce surgical risk). 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.

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) (blue dye may be added to the balloon liquid 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 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 doctor and 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 than 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 reduce your food intake 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/dietician and doctor.

Week 2:

At the beginning of week 2 you will advance your diet according to your nutritionist/dietician 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/dietician 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.
- 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 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 12 months after it is placed. The risk of balloon deflation increases if it is left in place longer than 12 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 12 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 12 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.

MR Conditional

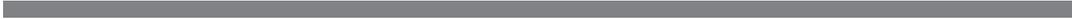
The Spatz3 Adjustable Balloon System® has been tested safely in a 3T MRI scanner. Patients with implanted Spatz3 adjustable balloon systems may safely undergo MRI scanning with a 3T scanner.

Questions/ Assistance:

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

For any assistance please contact:
Spatz FGIA, Inc
1801 S Perimeter Rd
Suite 130
Fort Lauderdale, FL 33309
USA

Tel: 1-516-303-0613
www.spatzmedical.com
info@spatzmedical.com







Spatz FGIA, Inc
1801 S Perimeter Rd, Suite 130
Fort Lauderdale, FL 33309, USA
Tel: 1-516-303-0613
www.spatzmedical.com
info@spatzmedical.com