

"I lost 41 kg in 12 months. Thanks to the 1 year Spatz system, I have changed my ways and lost an additional 3 kg even after the balloon was removed"

Ms. Barbora Majerova was implanted with the Spatz™ Adjustable Balloon in October 2009



"After 1 year, I have changed my eating habits and lost 45 kg. I am ready to go on without the balloon"

Mrs. L. Sperlova was implanted with the Spatz™ Adjustable Balloon in October 2009



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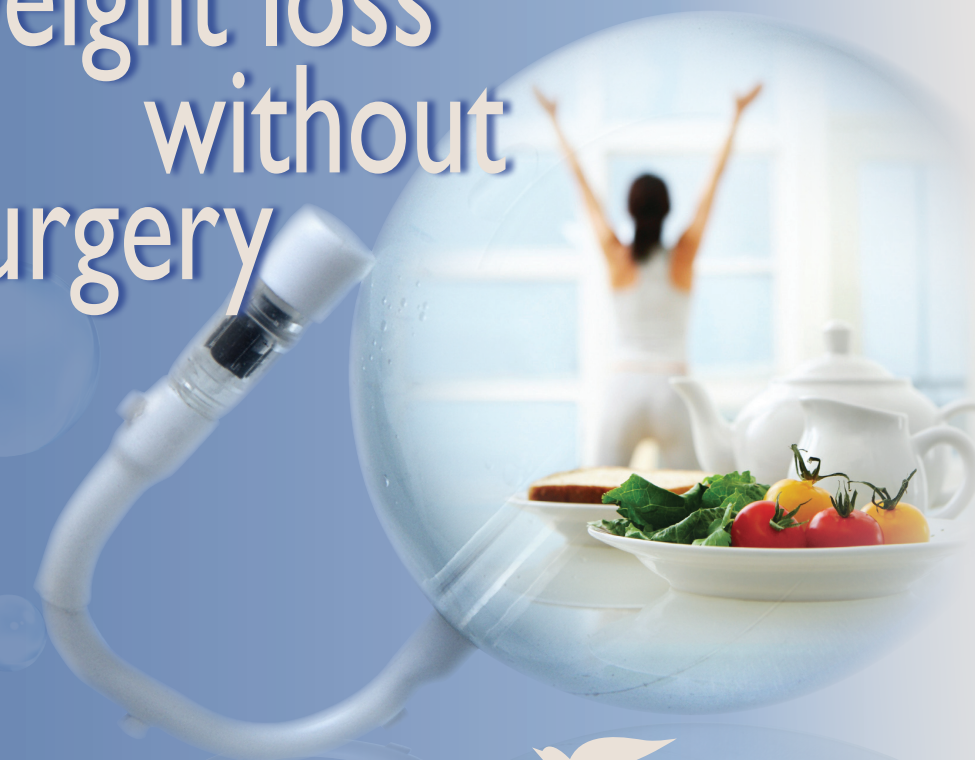
CAUTION: This device restricted to sale by or on the order of a physician. The product has obtained CE Mark. It is not FDA approved or available in the United States.

The Spatz Adjustable Balloon System® contains no latex or natural rubber materials.



SPZ-TM-111-B

Weight loss without Surgery



Obesity a worldwide epidemic

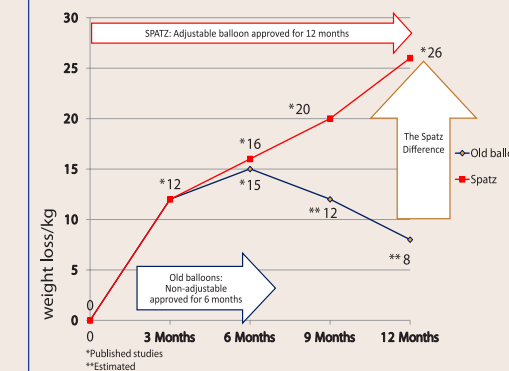
As you are probably aware, obesity is the number one worldwide epidemic. There are three hundred million obese and 1 billion overweight people worldwide. With all of the media attention, people are becoming more aware of the health hazards associated with being overweight or obese. Heart disease, stroke, cancer, diabetes, and hypertension are among the consequences of obesity. Commercial weight loss systems are expensive, and unsupervised dieting can be a very difficult and frustrating experience. Given the dangers associated with obesity surgery, non-surgical solutions have been growing in popularity.

Intragastric Balloons

Intragastric balloons in conjunction with a supervised diet and behavior modification program can help you achieve the health and aesthetic benefits associated with weight loss. More than 17 years of experience with intragastric balloons have reported modest successful weight loss and patient satisfaction. Yet, current intragastric balloons have not received worldwide acclaim nor have they gained popularity. The reason is twofold: Current balloons are not adjustable and lose their effect after 3 months; and current balloons must be removed at 6 months.

Why is the Spatz Adjustable Balloon System (ABS) different than other Balloons?

- Spatz is the an adjustable balloon. Other balloons offer one balloon volume that is not changed over the course of 6 months. Doctors try to inflate as much as possible in order to get the best result. Higher balloon volumes can be more uncomfortable. Generally, the effect of the balloon wears off after approximately 3 months, and less weight is lost over the remainder of the implantation period. With the Spatz ABS, the unique inflation port allows balloon volume additions or subtractions after the implantation. This allows your Doctor to start at a lower volume initially (less uncomfortable), and then increase the volume when you feel the effect wearing off.



This can be done multiple times. Patients who are intolerant can have their balloon volumes diminished. This translates to comfort, and greater weight loss.

- SSpatz is approved for 1 year implantation. Other intragastric balloons must be removed by 6 months. The Spatz balloon is approved for 12 months That means more weight loss, more behavior modification and longer lasting results after balloon removal. Longer implantation time with other balloons does not produce further weight loss, as the stomach adapts to the stagnant balloon volume. The potent combination of adjustability and 1 year implantation time separates the Spatz intragastric balloon from the rest.



How do intragastric balloons work?

The saline filled balloon occupies about one third of the stomach cavity. This decreases the quantity of food that the stomach can hold. The presence of the balloon also interferes with stomach emptying, such that food stays in the stomach longer. Together, these effects promote diminished appetite and early satiety with lesser food quantities.

The Program

Although you will have a feeling of fullness and your stomach capacity will diminish, that alone is only part of the program. Your physician along with a dietician/behavior modification specialist will meet with you during the course of the implantation period to help you modify your eating behavior. Food choices and lifestyle modifications will be easier to enforce with the Spatz balloon in place. Compliance with this program and at least once monthly visits with your dietician/behavior modification specialist will enhance your ability to succeed and maintain weight loss after the balloon is removed.

How is the Spatz balloon procedure performed?

A standard endoscopy with sedation is performed. If no abnormalities are found, the balloon is inserted via the mouth into the stomach – all under sedation. Once

inside the stomach, the balloon is filled with sterile saline through a small filling tube attached to the balloon. Placements of the balloon and adjustment procedures take approximately 10 minutes, after which patients are monitored for approximately 1 hour and then sent home.

For whom is the intragastric balloon suitable?

The intragastric balloon is designed to assist with weight loss in people who have approximately 10 kilograms or more of weight to lose, or those individuals with a BMI > 27, or are not suitable candidates for weight loss surgery. The use of the balloon may assist in reducing weight prior to any surgery, thereby diminishing operative risk.

How long does the Spatz Balloon stay in the stomach?

The Spatz Balloon can remain in the stomach for 1 year. While you are using the balloon, your physician will prescribe a course of oral medication to reduce your stomach acid (this will reduce the possibility of stomach irritation and damage to the balloon).

How much weight can I lose with the gastric balloon?

It is important for you to understand that the intragastric balloon is a tool to aid weight loss and must be used in conjunction with diet, exercise and a behavior modification program. The amount of



weight you lose and maintain will depend on how closely you follow your diet and adopt long-term lifestyle changes. Average weight losses of 12 to 15 kg over 6 month periods have been reported with other intragastric balloons. The Spatz balloon patients have reported an average of 25 kg weight loss at 12 months in our clinical study.

What are the possible side-effects associated with the intragastric balloon?

It is very likely that the presence of the balloon in the stomach will cause nausea, vomiting or abdominal pain, of varying intensity, for several days after placement. Your physician will prescribe medication to help minimize these potential effects, but these can persist during the first week. There exists the possibility that you will lose only a small amount of weight or lose no weight at all while using the balloon. Of course, your commitment to dietary and behavioral changes will determine your success. There is also a chance that unhealthy, uncontrolled weight loss

will occur and create adverse health consequences. Be sure to speak with your physician about this.

Will I be able to feel the balloon in my stomach?

There will be discomfort during the first few days after the procedure. From then on, the intragastric balloon will give you a feeling of fullness.

How long will it take to recover after the procedure?

You should plan at least three days of inactivity to recover from the procedure. You will be able to resume normal activity sooner or later than this depending on how quickly your body adjusts to the balloon.

Does the gastric balloon require frequent visits to my doctor after the procedure?

The follow-up program is critical to success of the balloon and in learning new lifestyle skills. You will meet with your doctor or dietician/behavior modification counselor at least once-a-month while the balloon is in place. During this time your progress will be evaluated and you will learn valuable principles of health, nutrition and exercise that will provide you a foundation for long-term success.

Are there any medication restrictions?

Aspirin, and other anti-inflammatory medications such as ibuprofen and many other NSAIDs are not permitted even in small quantities even occasionally.

How often will my balloon volume be adjusted?

When you feel less balloon effect (resumption of appetite) or when weight loss diminishes, you can have your balloon volume increased. Gastric balloon effect diminishes after 3 months, which is when you can expect to have your first balloon adjustment. It can be done as often as needed, with a simple endoscopy procedure. The balloon volume can also be decreased in cases of balloon intolerance.

How will the intragastric balloon be removed?

The Spatz balloon is removed in the same way it was placed, via the esophagus and mouth using endoscopy under sedation. The procedure takes less than 15 minutes, with about an hour recovery time before being sent home.

Will the intragastric balloon limit my activities?

During the first week of the procedure you should not plan any heavy activities. Once your body has adjusted to the balloon you can continue your normal activities. Starting a regular exercise program is highly recommended and will improve your success.



Can I eat anything I want? Are there any food restrictions?

You will not feel like eating as much as you used to. In addition, if you eat fatty foods or sweets, you may feel unwell. Excessive overeating while the balloon is in place can prove dangerous.

Will I Regain My Weight after the Spatz ABS System Is Removed?

The balloon creates a feeling of fullness in your stomach which helps you comply with the diet. Following the prescribed diet and changing your eating habits over the implantation period will help you maintain weight loss after balloon removal. Patients who follow the prescribed program and visit the dietician/behavior modification specialist regularly during the implantation period will have a better chance of weight loss maintenance after the balloon is removed. Behavior modification experts believe that the longer the balloon is implanted (along with behavior modification sessions) the longer lasting the results after the balloon is removed.

Are there Risks Associated with Using the Spatz ABS System?

As with all medical procedures, there is a risk of adverse reactions to the medications used and type of procedure involved. This can vary with individuals. As with other gastric procedures, there is the risk of injury to the lining of the digestive tract by



the endoscope or the balloon with all of its insertion apparatus. This could result in inflammation, ulceration, bleeding, perforation or obstruction; requiring medications, device removal or surgery. Balloon fluid could become infected, and release into the stomach could cause an intestinal infection with fever, cramps or diarrhea.

Spontaneous deflation of the balloon releases a blue color into the stomach which turns your urine green. If this happens, the balloon should be removed immediately. However, the risk of bowel obstruction exists and could lead to surgical correction. This could lead to death if untreated. Please contact your physician immediately if you have any unexplained symptoms. We wish you a successful outcome.