Treatment Guide

Spatz3, the only Adjustable Gastic Balloon, delivering the highest weight loss results.
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Are you struggling losing weight?

If you have struggled with losing weight, you are one of the millions of people who face this challenge every single day. Traditional diets may be challenging, and many of us require additional help that a routine diet is unable to provide.

Diets rarely leave a lasting effect on our eating habits and weight maintenance. Spatz’s approach to successful weight loss focuses on keeping the weight off given the challenge of achieving this with diet alone. Failure rates for diets alone are in the 95% range and people often think of surgery as the only other option for reaching their weight loss goals.

There is, however, a better way to make a lasting change in your eating habits and health other than surgery.
A revolutionary treatment method for weight loss

The Spatz3 Adjustable Gastric Balloon is a non-surgical treatment for weight loss that will help you lose weight and regain control of your health. Used in harmony with a professionally supervised program of behavior modification and diet, it can help you achieve and maintain the health and aesthetic benefits associated with weight loss. The revolutionary adjustable balloon treatment for weight loss allows adjustment of the balloon volume and longer implantation time – features that are exclusive to the Spatz3 Adjustable Gastric Balloon.
The Spatz3 is placed in the stomach and occupies approximately one-third of the stomach’s volume. This causes the stomach to empty very slowly, keeping food in longer than usual. The food builds up over time, producing “signals” that alert the patient that food is abundant in the stomach. As a result, the patient can learn to read these signals and develop healthier eating habits while losing weight!

**Stomach Capacities - 2 Hours After A Meal**

This stomach is still full with food and the balloon

This stomach is almost empty
Over the past 30 years, more than 400,000 people have lost an average of 10-30 kg (22-66 lbs) of weight with a gastric balloon’s assistance. Your motivation and willingness to comply with dietary changes and behavior modification are important factors in your success with the Spatz3 Adjustable Gastric Balloon.

Patients with certain medical conditions may not be eligible for a gastric balloon implantation. Your decision to undergo gastric balloon therapy must be made in consultation with a qualified physician.
Motivation

Although the gastric balloon can be a useful tool for overweight and obese patients, the weight does not come off by itself. Motivation and cooperation are crucial factors in achieving successful and long-lasting weight loss.

Compliance

A successful outcome requires compliance with diet and behavior modification. Our unique system allows adjustment of the gastric balloon volume at varying times during the treatment period. All of these require the patient’s compliance. People who struggle with portion control and have tried appetite suppressants and supplements in the past and have failed in their attempts at weight reduction will find that the gastric balloon can lead to successful weight loss.
Consultation

The decision to undergo gastric balloon therapy must be made in consultation with a qualified physician. Certain conditions would exclude gastric balloon implantation. Here is a partial list of those conditions:

- Some kidney, liver, lung, and cardiac disease
- Previous esophageal or stomach surgery
- Chronic NSAID, antiplatelet, or anticoagulant medication use
- Large Hiatal Hernia
- Substance or alcohol abuse
- Pregnancy
- And other conditions

You must confirm with your physician exactly what to expect when you undergo gastric balloon therapy.
What to expect?

The Spatz3 Adjustable Balloon procedures are done in endoscopy units, that may be within a clinic or within a hospital. An intravenous line is placed for the administration of sedating medications – this is so you will not feel any discomfort. An endoscope is placed through your mouth into the stomach, and the balloon is inflated in a 15-minute procedure. Following a one-hour recovery period, you will be discharged home with your designated driver.

During the first few days, most patients will be uncomfortable and experience nausea, vomiting, or pain. Your doctor will prescribe medications to help manage these symptoms - they generally diminish over a number of days.

You will have the unique opportunity to change the volume of the Spatz3 balloon. In essence, the Spatz3 volume can be customized (adjusted) to your specific needs, as opposed to all other gastric balloons that are non-adjustable. That is why the Spatz3 balloon has much higher success rates than non-adjustable balloons. These adjustment procedures and the removal procedure are also performed under sedation just like the implantation procedure.
What if I’m too uncomfortable?

About one in 10 people with gastric balloons, of all varieties, need to have their balloon removed because it is too uncomfortable for them. Unless they have a Spatz balloon which has a unique feature that allows the balloon volume to be made smaller as needed. Unlike non-adjustable balloons, the Spatz3 volume can be customized to your needs.

What if the balloon stops working for me?

About half the patients with gastric balloons, of all varieties, will complain that the balloon effect wears off after several months. With the Spatz3 Balloon, we can increase the balloon volume to rejuvenate its effect and help you lose more weight. The Spatz3 Adjustable Gastric Balloon is the most effective weight loss balloon on the market due to our unique adjustability feature. When compared with other gastric balloons in the FDA Trials, Spatz has the highest weight loss results and highest success rates!
Thanks to our unique adjustability feature, the Spatz3 Adjustable Gastric Balloon had an 84% success rate, whereas the closest competitor had a 48% success rate. Additionally, the Spatz3 Adjustable Gastric Balloon achieved 53.6% excess weight loss - almost one and a half times higher than the next highest competitor, and coming close to the results of bariatric surgery. The Spatz3 Adjustable Gastric Balloon provides more effective weight loss than any other gastric balloon.

However, please understand that the gastric balloon is a tool to help reach weight loss and should be used in conjunction with a planned diet, exercise and a behavior modification program. Average weight losses of approximately 35 lbs (16 kg) to 55 lbs (25 kg) have been reported with the Spatz3 Adjustable Gastric Balloon.
Please review the following tips to help you prepare for your Spatz balloon implantation:

**Fast from midnight**
The night before the procedure: For those having their implantation procedures in the afternoon, it may be difficult to fast from midnight the night before until the afternoon. In this case, you may have clear liquids in the morning and fast for six hours before the procedure.

**Get a good night’s sleep**
Sleep is always beneficial, so get some good shut-eye the night before the implantation.

**Arrange for someone to escort you home post-procedure**
The procedure itself takes approximately 15 minutes and you should be on your way home with the help of an escort within an hour after the procedure. Since you should not drive, please ensure that your escort is able to take you home.
Lean on family and friends for support
Use the support of your friends and family, especially during the first few days after the balloon procedure. You may need to arrange help for child-care for 4-5 days, as you will feel weak and may have difficulty managing children.

Take off 4-5 days of work post-procedure:
Give yourself time to rest after the balloon procedure. On average, 4-5 days is the amount of time needed to recuperate. Some people need 6-7 days, or more, and others may need only 1-2 days.

Be in touch with your doctor and clinic
Please be in contact with your doctor/clinic whenever you have a question or are in need of support.
Enter the Spatz balloon treatment with the correct attitude
Remember that this is a proven program whose success depends on the balloon, dietician follow-up, clinic support and your cooperation. It is a partnership; when everybody does their part, the chance of success increases dramatically. The Spatz3 Adjustable Gastric Balloon has the highest success rates of all intragastric balloons (84%, compared with 25%-48% with other balloons), and you too can be successful. Success is not just weight loss, but a change in eating habits, lifestyle and attitude towards food. You can achieve this when we all work together.

We hope this was helpful.
Good luck on your journey with the Spatz3 Adjustable balloon!
Here is what you can expect to experience during the first days after the Spatz balloon implantation: the stomach receives the balloon and reacts to it – we call this phase 1.

**Phase 1:**

For approximately the first 3-5 days after your balloon implantation, you will experience symptoms and discomfort and it will be difficult to eat. Most patients commonly experience symptoms such as, nausea, vomiting, pain and heartburn/acid reflux. This phase is difficult on the one hand, but on the other hand, it is helpful because it gives a kickstart to your weight loss. The balloon basically does the work for you (it won’t let you eat), and you accommodate to the balloon’s presence in your stomach. For a minority of patients this will last only 1-2 days or it may last 1 week or more.
Here is a more in-depth explanation of the symptoms that you may encounter in Phase 1:

A. **Weakness/Dehydration:**
Everyone experiences weakness/dehydration to some degree because food/liquid intake is minimal. This is to be expected for the first 3-5 days, give or take, and it will pass. Please be in contact with your doctor/clinic.

B. **Nausea:**
About 90% of people experience nausea. This is to be expected for the first 3-5 days, give or take, and it will pass.

C. **Vomiting**
About 20% of people experience vomiting, but it will pass. This needs to be reviewed with your doctor and it is best to keep track of the number of times you vomited per day. If the number is less than the prior day, then you are heading in the right direction. Over the ensuing days, as the number decreases, you will be able to see the 'light at the end of the tunnel.' In some cases, intravenous hydration may be needed to correct dehydration.
**Abdominal Pain/Spasms:**
About 20% of people experience abdominal pain or spasms, but it will pass. This needs to be reviewed with your doctor. In order to alleviate abdominal pain or spasms, your doctor may give you antispasmodic medications. They take the edge off and make the process more manageable. Please be in contact with the clinic and doctor to let them know what you’re experiencing and they will help you get through this. It will eventually pass.

**Heartburn/Acid Reflux:**
This may last for 3-5 days. All patients take a PPI (proton pump inhibitor) medication which lowers stomach acid and helps alleviate heartburn. The PPI can be taken once or twice a day. Another option is to take an antacid (ex: Maalox) for immediate relief (but it is not long-lasting). It is possible to take both, but you must consult with your doctor first.
Phase 2:

After approximately one week, you will transition into phase two. During Phase 2, your stomach will have gotten used to the balloon and the symptoms will progressively subside. You will begin to eat and start to regain your strength. It is at this time that you will learn to work with the balloon. You don’t suffer from the balloon (like you did in Phase 1), rather, you will learn to understand the signals the balloon sends you- as discussed below.

What is happening in Phase 2? The balloon causes your stomach to accumulate food – the accumulation of food causes minor symptoms such as burps/belches, fullness, bloating or minor discomfort. We call these minor symptoms “signals” and these signals are the key to your behavior modification. The signals start out stronger and decrease in frequency and severity over time. When you look at the entire process, you can see and appreciate the following: the balloon starts with strong/difficult symptoms in the first week during Phase 1, followed by less strong symptoms in the transition phase, followed by phase 2 signals, which also start out stronger and diminish over time. That means that the balloon does more at the beginning and less over time. It will be easier to respond to the stronger and even less strong symptoms, and progressively harder to respond to signals and even harder to weak signals. That is your job – react to less over time. That is how you develop tools to negotiate life without a balloon. It takes time – so use your time with the balloon effectively.
The following table shows the progressive effects of the balloon. It represents average timing and average effects, which vary widely among individuals.

<table>
<thead>
<tr>
<th>Phase</th>
<th>Approximate Timing (varies with individual)</th>
<th>Symptoms or Signals</th>
<th>Food Intake Potential</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase 1</td>
<td>Week 1</td>
<td>Strong Symptoms/Difficult</td>
<td>None to limited</td>
<td>Balloon prevents eating</td>
</tr>
<tr>
<td>Transition</td>
<td>Week 2-5</td>
<td>Symptoms decrease</td>
<td>Begin eating</td>
<td>Balloon allows some eating</td>
</tr>
<tr>
<td>Phase 2 early</td>
<td>Week 2-12</td>
<td>Signals strong/medium</td>
<td>Eat correct amounts</td>
<td>Balloon allows correct eating</td>
</tr>
<tr>
<td>Phase 2 late</td>
<td>Week 12 and beyond</td>
<td>Signals weaken/disappear</td>
<td>Eat more</td>
<td>*May overeat</td>
</tr>
<tr>
<td>Pre-Removal</td>
<td>months prior to removal 1-2</td>
<td>Signals weaken/disappear</td>
<td>Eat much more</td>
<td>*May overeat</td>
</tr>
</tbody>
</table>

*Overeating will cause restart of signals and symptoms depending on amounts ingested
Adjustability
ADJUSTABILITY
Up and down-adjustment

Up Adjustment
Around the 4th month of your gastric balloon, you may begin to experience a weight loss plateau or even the beginning of weight regain. With other, non-adjustable gastric balloons, you will have to work much harder just to keep off the weight you have already lost. With our unique adjustability feature, we can increase your balloon's volume to help rejuvenate the balloon's effect. This can help most patients avoid the weight loss plateau and yield extra weight loss. As a result, we can extend your treatment for up to 12 months* and increase your chances for a successful outcome.

*8 months in the US market

Down Adjustment
Alternatively, if the balloon becomes uncomfortable or intolerable, the volume of your balloon can be reduced to ensure a comfortable fit. Intolerance is reported to occur in up to 10% of all gastric balloon patients - only the Spatz3 volume can be reduced, offering the safest and most comfortable weight loss system.

Together, these exclusive features offer our patients the highest success rates in the world!
Well done, you made it to the end of your journey with the Spatz3 Adjustable Gastric Balloon!

**Balloon removal process:**
The balloon’s removal will be a similar process to its implantation. It will take 15 minutes out-patient procedure, under sedation, followed by a one hour recovery time. Your doctor will endoscopically remove the fluid from the balloon and then remove the deflated balloon from your stomach. You should not have any symptoms unless you overeat in the days following the removal - please discuss with your dietician.

**Important reminders:**
• There is a special 3-day restricted diet prior to the procedure (dietician will instruct you)
• Please arrange for someone to drive you home after the procedure

Give yourself credit for all the hard work and effort you put into the process. Keep in mind that although the balloon did most of the work during phase 1 (the first week or so), you then transitioned into phase 2 and took control. You learned how to anticipate signals and prevent symptoms. In essence, you have learned to manage your eating and are now ready for the balloon removal.

Again, we commend you for your efforts to take on the challenge of losing weight and living healthier.
Let's prepare for life after the balloon removal. By now, you have established eating patterns and a healthy lifestyle, which you've been following for some time.

Here are 10 Tips to Stay Healthy Post Spatz Balloon:

1. **Stay Away from Sugary Beverages:**
   Eliminate beverages with high calories and sugars. They have little nutritional value and will promote weight gain.

2. **Make Physical Activity a Priority:**
   Aim for a period of physical activity daily. It could be anything from walking to light calisthenics, swimming, biking or even dancing- find what suits you best and try to have fun with it.

3. **Eat a Balanced Diet:**
   A mix of protein with fresh vegetables and some carbohydrates will help maintain lean body mass. During balloon treatment, it may have been difficult to eat salads and vegetables. Within 2 weeks after balloon removal, you may restart salads and vegetables.
**Be Kind to Yourself:**
If you feel like you have eaten too much over the past few days make sure to make the corrections needed, but don't beat yourself up over it. You have the power to eat properly and you can do it. Don't give up!

**When is the right time to stop eating?**
Set your food boundaries:
- based on your food intake from the previous week – in other words be aware of and take ownership of your food intake, and plan accordingly.
- during any meal - try to recognize when you feel full and stop eating at that point.

**Create New Healthy Habits:**
Create a daily plan that is constructive and productive. Idle time? Add an activity that improves your quality of life; an experience that you enjoy, and look forward to doing it.
Drink Plenty of Water:
Hydration is key to having a balanced diet and a healthy body. So, stay hydrated and drink more water.

Eat with purpose.
You are creating a healthy lifestyle for yourself. Only eat when your body is hungry and in need of nutritious food. That way you are developing a healthy relationship with food.

Get a Good Night’s Sleep
Hormone levels are altered when you don’t get enough sleep and can make you feel hungry. So, rest up and it’ll be easier to eat right.

Lean on friends and family for support:
We could all use some support. Let your family and friends know how you are doing and to make sure that they hold you accountable.

Wishing you the best of luck on your weight loss journey!
You can always come back to this app for healthy lifestyle tips.
Congrats!

You have officially begun your journey to reach a healthier lifestyle that will allow you to live life to the fullest. By making the necessary changes to your diet, your activity levels, and your overall lifestyle, you can achieve healthy lifestyle goals.

The Spatz3 Adjustable Gastric Balloon gave you the opportunity to develop tools, but you did all the work to reach your weight loss goals; we can’t wait to see where you go from here!

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