



A tried and trusted solution to failed diets, that avoids surgery and drugs

The health of the Nation

As our portions become larger and our way of life more sedentary, we are eating more and exercising less. The natural consequence of this trend is now seen in what many healthcare professionals call the obesity epidemic. It's a fact that European obesity rates have tripled in the last 20 years which, if nothing is done, will mean that nearly 1 in 5 people will be affected by 2010.¹

Many countries now face a major healthcare crisis. The link between obesity and serious health conditions is clear. Diabetes, heart disease, stroke, cancer and hypertension are all closely correlated with obesity and are also increasing, straining healthcare budgets. The more overweight we are, the worse the problems become.

Dietary advice of every kind is also on the rise, but diets alone rarely change long-term eating habits and many schemes have not delivered the anticipated successful weight-loss and long-term results they continually promise. Thousands of moderately obese people clearly need more help than can be provided with drug therapy or dietary advice alone. Such alternative solutions must combine the best of today's medical technology with proven principles for healthy lifestyle change.



Welcome to the BIB™ System

The BIB™ System is a medically supervised, internationally proven, professional System that will help you take control of your weight — without the risks of surgery or drugs.

It does so by helping you to feel full, thus reducing the urge for food, whilst you undertake a weight-loss programme with the help and support of a team of doctors and dieticians. Think of it like stabilisers on a bike, without which, learning to ride can be slow and painful. But with the help of its own 'training tool', BIB™ can help you transform your body in a safe and effective manner, improving your health and enhancing your life.

A System with two important parts:

The Intra-gastric Balloon: The BIB™ is a soft, silicone balloon that is inserted into the stomach and filled with sterile saline. The balloon is designed to partially fill your stomach, giving you a feeling of fullness. In medical terms this is called satiety. It will not only make you feel less hungry, but feel fuller more quickly after small meals. The balloon will be removed after 6 months.

With the help of the BIB™, you will have a better chance in adopting the lifestyle changes needed to lose weight.



Weight-loss Education: Experienced weight-loss professionals will consult with you and design a programme to help you successfully reach and maintain your weight-loss goals. Your team will be there every step of the way with encouragement and support. Such a team of experts may vary, but could include physicians, dieticians, physiotherapists and even psychologists!

During regularly scheduled meetings with your team, you will learn the principles needed to manage your weight and promote long-term health.

Some of these include nutrition, exercise, eating behaviours, and psychological issues related to food. While learning, you will be motivated by your success and more easily turn these principles into habits that will serve you the rest of your life.

What should my 'ideal' weight be?



Usually, people instinctively know when they have reached their 'ideal' weight. This is the weight at which people generally feel good about themselves, feel healthy and energetic, feel they can wear what's 'in-fashion' without feeling too self-conscious in public.

Not everyone looks or feels the same as each other, even at the same weight, so clinicians have worked out a way of expressing weight against relative health risks.

The most common measurement used for indicating whether a person is overweight is Body Mass Index (BMI).

BMI classifications are based on the relationship that body weight has on disease and death. Although weight is only one of many factors used to predict health risks, studies show a strong correlation between higher BMI and many serious diseases.

BMI Classifications

BMI	Classification
20-24.9	Normal
25-29.9	Overweight
30-34.9	Obese
35-39.9	Severely Obese
40 or above	Morbidly Obese

You can work out your own BMI by using the following calculation:

Your weight in kilograms divided by the square of your height in metres

$$\frac{\text{kg}}{\text{m}^2} = \text{BMI}$$

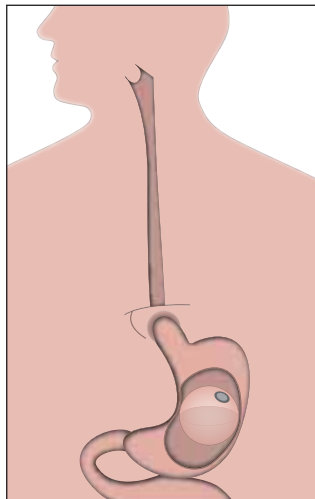
If you have a BMI of 30 or more, the BIB™ System could be the ideal solution for you. But please remember, this is only a guide. BMI does not distinguish between fat and muscle. It is possible for a heavily muscled individual to have a BMI in excess of 25 without increased health risks. Your doctor will be able to give you a much more accurate health assessment based on your BMI together with other relevant health factors.

What is the BIB™ gastric balloon and how is it inserted?

The BIB™ is a soft, seamless silicone balloon that's very strong and designed to resist the action of your stomach acid for at least six months.

- The balloon is filled with sterile saline, to which is added a blue safety dye to colour your urine in the extremely unlikely event of a leakage
- The fill volume is variable from 400ml to 700ml so your physician can adjust the balloon specifically for your own requirements

The deflated BIB™ balloon is attached to a soft tube and is passed through your mouth, down your gullet into your stomach during a simple 15-20 minute procedure called endoscopy.



You will be mildly sedated while the balloon is inserted and filled with saline to the appropriate volume. It's the weight of the saline that gives the balloon the appropriate 'presence' to give you a feeling of fullness. When this is done, the tube is removed through your mouth. Removal after six months is just as simple. A tube is passed through your mouth into your stomach and the balloon deflated. The deflated balloon is then pulled back out through your mouth again. Patients can be discharged home again within a matter of hours. Most need little, if any, time off work.

The BIB™ System offers many distinct advantages over conventional diets and weight-loss programmes. With the BIB™ you will:

- Have a feeling of fullness (satiety)
- Lose more weight than with other diet programmes
- Be supported by a team of medical experts
- Learn principles for long-term success
- Have the benefits of a non-surgical, non-pharmaceutical approach

Experts agree that successful weight-loss programmes should not only help you lose weight, but keep the kilos off over time. The BIB™ System combines a clinically proven way to reduce hunger with your own personal team of experts.

How much weight could I expect to lose?

Patients participating in the BIB™ System can expect to have significant weight-loss in the first six months. The amount of weight you lose and how long you maintain that weight-loss will depend on how well you adopt long-term lifestyle changes related to eating and exercise.

The following weight-loss results were achieved in published clinical studies using the BIB™ System.

Brazilian Study, 2004

323 patients;
average weight-loss
after 6 months: **15kg²**

Large European Study, 2005

2,515 patients;
average weight-loss
after 6 months: **20kg³**



Is the BIB™ System right for me?



To qualify for the BIB™ System you must:

- Be at least 18 years old
- Be obese with a BMI at least 30*
- Be ready to comply with a professional, medically supervised programme

*Use of the BIB™ System is not advised in patients with a BMI of less than 30, unless accompanied by other health problems associated with obesity that would be expected to improve with weight-loss.

In addition, there are certain medical reasons you may not be eligible for the BIB™ System. You may not be a candidate for the procedure if any of the following conditions are present:

- Previous history of upper gastro-intestinal surgery, obstruction, adhesive peritonitis or large hiatus hernia
- Severe renal, hepatic or pulmonary disease diagnosis
- Chronic, long-term steroid treatment
- Unwillingness to adopt the dietary habits critical to the success of the therapy
- Drug or alcohol addiction in the last 12 months
- Pregnancy
- Breast feeding

As with all medical procedures, there are potential risks of unforeseen, unknown or adverse reactions to medications and the procedure itself. Please discuss your questions and expectations about the BIB™ System with your doctor in order to properly evaluate the benefits versus the possible risks.

How should I prepare for the procedure?

As an eligible BIB™ candidate, you will begin by meeting with your doctor to discuss the programme in detail. Once you have scheduled a date for your procedure, you will begin meeting with your support team and learning the principles that will become the basis of your long-term success. Your support team may include the following:

- physician
- dietician
- physiotherapist
- psychologist
- other specialists

You will then undergo a series of medical tests to evaluate your overall health. You will meet with your physician and dietician to review the pre- and post-placement expectations and instructions.

Important Reminders:

- No solid foods or liquids 12 hours prior to the procedure
- Stock your kitchen with the necessary post-procedure foods and liquids as instructed by your dietician
- Plan for at least three days of inactivity after the procedure
- Arrange for someone to drive you back home from the treatment center and to be around to give you support for a couple of days



Success
with less

The Day of Placement

On the day of the procedure, your team will prepare you for the endoscopic placement of the balloon, which generally takes about 15-20 minutes. You will be sedated while the deflated balloon is inserted into your stomach through your mouth. After the balloon is placed in the correct position and filled with saline, you will remain in the clinic for observation until the doctor discharges you into the custody of the person who will take you home. (As you may still be feeling the effects of the sedation).

Adjusting to the BIB™

The first few days will be uncomfortable as the stomach gets used to the presence of the balloon. You may experience nausea, vomiting, bloating, diarrhoea and cramping until your body adjusts. These conditions are normal and should be expected. Your physician will provide strict instructions for your hydration regimen during this period. For the first day you will probably only manage a few sips of water, in the days that follow it is critical that you drink plenty of water and avoid eating any solid foods.

You will be restricted to a liquid diet for the first three days, which might include the following:

- **juices**
- **milk**
- **thin soups or broths**
- **gelatins**

Please avoid the following foods:

- **coffee**
- **fizzy drinks**
- **fatty foods**
- **chocolate**
- **ice cream**

Important Reminders

- Do not engage in any physical activity for the first 24 hours
- Drink cold liquids in small amounts, beginning with a teaspoon, and slowly increase the amount of the liquid as you are able. If liquid is taken in large amounts there is a higher risk of nausea and vomiting
- A doctor will be on call the first 24 hours to handle any reactions or distress you may feel



...for
more
from life

Working up to solid foods

After a few days on a liquid diet, you will be ready to begin the transition to solid foods. Prior to solid foods, you will graduate to semi-solids. How quickly you make this transition will depend on your progress and how well your body is tolerating the liquids. It is important to make the transition slowly and not try to rush the adjustment process. Some of the foods your dietician may prescribe at this point are porridge, thicker soups and fruit purées.

Beginning your new programme

At this point you will begin regular meetings with your medical support team. Your physician, dietician, and other experts will play important roles in evaluating your needs in consultation to create a customised programme. Your appointment schedule will be decided with your team, however it is critical that you attend all meetings. Your success with the BIB™ System will depend on how committed you are to learning from your support team and adopting the principles of good health into your daily life. You will receive instructions on your initial solid-foods nutrition regimen with calorie restrictions. This initial prescription may be adjusted over time during subsequent meetings with your dietician.

The next six months

After the first two weeks, your body will have adjusted to the BIB™, you will be following a regular nutrition plan, and you will have resumed your normal activities. Over the next six months it will be critical to meet with your doctor to measure your weight-loss progress and your support team for education and training. This period is important to prepare you for maintaining weight-loss after the BIB™ is removed.

Remember, the BIB™ is only a 'training tool', like stabilisers on a bicycle. The BIB™ gives you a window of opportunity to adapt to the lifestyle changes you must make in order to maintain your ideal body weight. The following guidelines will help you be more successful:

- Meet regularly with your medical team to stay motivated and committed to the programme. Experience shows that those who attend the scheduled follow-up meetings have the best short- and long-term results
- Keep a diary of what you eat and how much you exercise
- Make your new nutrition plan a long-term lifestyle change

During the period the BIB™ is implanted, be careful to observe and report any unusual changes in the way you feel. If you feel nauseous for a longer period of time than the initial few days, let your doctor know immediately.



BIB™ removal

After six months, the BIB™ will be removed in a 20-minute procedure similar to that of the placement. During the removal procedure, you will be sedated, and your doctor will remove the saline from the balloon before removing the deflated balloon from your stomach.

Important Reminders:

- No solid food 24 hours prior to the procedure
- No liquids 12 hours prior to the procedure
- Arrange for someone to drive you back home from the treatment center and to be around to give you support for a couple of days

After removal of the BIB™, you will still be under the supervision of your support team. With their continued help, you'll be on your way to successful and sustained weight-loss.

Like stabilisers on a bike, the BIB™ helps jump-start the process, but now you will have new tools and a new outlook. You will be successful and you will know how to continue that success. The balloon may be gone but your desire to continue the life you now enjoy will motivate you to stay on the path to health and happiness, and never go back.



Some frequently asked questions

Q: How much weight will I lose?

A: You can experience significant weight-loss averaging between 15-20 kilos; however, your results will depend on how well you follow the programme and adjust your eating habits.

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

A: There will be discomfort during the first few days. After that, the primary sensation of the BIB™ is a feeling of fullness (satiety).

Q: Are there side-effects or complications with the BIB™?

A: The first three days can be the most difficult. Cramping, nausea and vomiting are normal and should be expected. It is very important that you follow your doctor's instructions and drink plenty of fluids after the first day. Medication will be made available to help ease the discomfort.

Q: How long will it take to recover after the procedure?

A: 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 BIB™.



Well
satisfied

Q: How will the weight-loss results compare with other diet programmes?

A: You can expect to lose more weight with the BIB™. Because the BIB™ gives you a feeling of fullness (satiety), you are better able to control your eating and make healthy changes in your habits.

Q: Does the BIB™ require frequent visits to my doctor after the procedure?

A: The follow-up programme is critical to success with the BIB™ and in learning new lifestyle skills. You will meet with your physician and support team at least monthly while the BIB™ 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.

Q: Does the BIB™ limit activity?

A: The first week you should not plan any heavy activity. Once your body has adjusted to the BIB™, you can continue your normal activities. Starting a regular exercise programme is highly recommended and will improve your success.

Q: What happens if the BIB™ leaks?

A: In the extremely rare event of a leak, you will notice a change in your urine colour (it will be greenish due to the non-toxic blue dye we add to the saline in the balloon). Although very uncommon, this can be a serious situation. If you notice a change in urine color, you

must call your doctor immediately. If the BIB™ deflates, it may pass through your body naturally, but in some cases it may need to be removed by your doctor.

Q: Can I drink alcohol?

A: Although alcohol consumption in moderation will not affect your gastric balloon, the extra calorie intake won't help with your weight-loss programme! Always follow the advice of your doctor/dietician.

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

A: You will not feel like eating as much as you used to. In addition, if you eat fatty foods or sweets, you may feel sick. Excessive overeating while the BIB™ is in place can be dangerous and can result in a serious medical condition.

Q: How is the BIB™ removed?

A: The BIB™ is removed through the mouth in the same manner it was inserted. The 20-minute procedure is performed under mild sedation.

Q: Must I participate in the follow-up visits to be successful?

A: Yes, the BIB™ gastric balloon is only part of the solution to help change your lifestyle. Taking part in the programme will give you the education and support to change your lifestyle habits and have a better chance for long-term success.





www.loseweightgainlife.co.uk

Helping patients take control of their lives



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Caution: This device is restricted to sale by or on the order of a physician. The BIB™ intragastric balloon contains no latex or natural rubber materials.™ mark owned by Allergan, Inc. © 2007 Allergan, Inc. Irvine, CA 92612. All rights reserved. This device is CE marked.

References:

1. World Health Organisation - Europe "10 things you need to know about obesity". WHO European Ministerial Conference on Counteracting Obesity, Istanbul, November 2006.
2. Sallet JA, Marchesini JB, Paiva DS *et al.* Brazilian Multicentre Study of the Intragastric Balloon. *Obesity Surgery* 2004; **14**: 991-998.
3. Genco A, Bruni T, Doldi SB *et al.* BioEnterics Intragastric Balloon: The Italian Experience with 2,515 Patients. *Obesity Surgery* 2005; **15**: 1161-1164.