

Treating Obesity

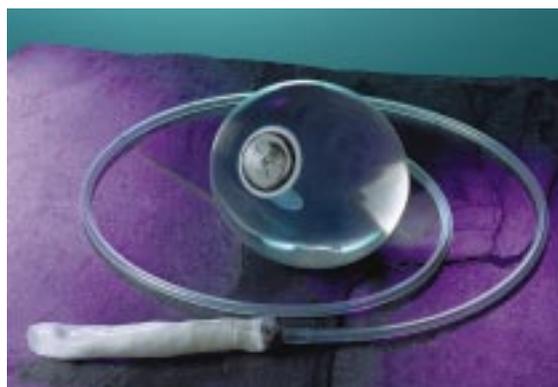
You may know from personal experience that unsupervised dieting to reduce weight is a very difficult process. In recent years the question of being and remaining slim has received plenty of attention in the media. Millions of people throughout the world are attempting to reduce and control their weight, with varying degrees of success.

Being overweight or obese is unhealthy. It can cause physical problems and diseases such as heart and vascular disease and diabetes. In addition, it may have major psychological consequences such as a negative self-image.

With the development of the BioEnterics® Intra-gastric Balloon (BIB®) System comes a weight loss aid which, in conjunction with a supervised diet and behavior modification program, can help you achieve the health and aesthetic benefits associated with weight loss.

What Is the BIB System?

The BIB System consists of a soft, expandable balloon, the placement tube and a filling system so a physician can orally insert the weight loss aid.



The BioEnterics Intra-gastric Balloon (BIB) System

Once inserted in the stomach, the empty balloon is filled with sterile saline.



The BIB System positioned within the stomach

When full, the balloon is too large to pass into the bowel and will now float freely in the stomach.

How Does the BIB System Work?

The BIB System is designed to make compliance with a supervised diet and behavior modification program easier. The balloon partially fills the stomach and patients report that they have a feeling of fullness.

How Is the BIB System Balloon Placed in the Stomach?

The balloon is introduced into the stomach through the mouth without the need for surgery. The physician conducts an initial examination of the stomach using an endoscopic camera. If no abnormalities are observed, the physician proceeds with placement of the balloon through the mouth and down the esophagus into the stomach. The balloon is made of a soft and pliable silicone elastomer material and is inserted while in its smallest, deflated form. The swallowing process is made easier with the help of anesthetics applied topically to numb the throat area. Muscle relaxing medications are also used.

Once the balloon is inside the stomach, it is immediately filled with sterile saline through a small filling tube (catheter) attached to the balloon. Once filled, the doctor removes the catheter by gently pulling on the external end. The balloon has a self-sealing valve, and at this point the balloon is floating freely in the stomach.

Placement times vary but it will usually take 20-30 minutes, after which you will be monitored by the physician for a short time and then may return home.

Who Can Use the BIB System?

The BIB System is designed to assist with weight loss in people who are at least 40% above their ideal weight (as defined by the Metropolitan Life Insurance 1983 Weight and Frame tables) and who have failed to obtain prolonged weight loss with other weight control programs.

The BIB System may be particularly useful for people considered too overweight or at increased risk for vital surgery. The use of the BIB System to successfully reduce weight prior to surgery may help reduce the risks associated with surgical procedures on overweight patients.

How Long Is the BIB System Balloon Used?

The balloon currently can be used for six months. Longer periods of use are not recommended. Over time the acidic content of the stomach will weaken the balloon material and cause the balloon to deflate. Should your physician recommend use of the balloon for longer than six months, it is necessary that the balloon be replaced with a new one when the six-month interval has been met.

While you are using the balloon, your physician may prescribe a course of oral medication to reduce your stomach acid (this may reduce the possibility of stomach irritation and damage to the balloon).

What Happens if the BIB System Balloon Deflates Spontaneously?

If the balloon deflates before a scheduled removal you may or may not be aware that it has occurred. Your physician may place a colored dye inside the balloon in order to help you clearly identify early deflation by a change in the color of your urine.

The balloon is small enough that it may pass through the intestines and leave the body naturally, but there have been some cases in which it has had to be removed from the bowel surgically. If you suspect a deflation, you must notify your physician immediately.

How Will the BIB System Balloon Be Removed?

The balloon is normally removed in the same way it was placed, via the esophagus and mouth. Prior to removal, you will be given a muscle relaxant and a topical anesthetic will be applied to numb the throat. Using an endoscopic camera, the physician will introduce a catheter through the mouth and into the stomach. The balloon will then be punctured and deflated. Once the balloon is deflated it can be grasped and removed.

How Much Weight Will I Lose with the BIB System?

It is important for you to understand that the BIB System is an aid to weight loss and must be used in conjunction with a prescribed diet and behavior modification program. Therefore, the amount of weight you lose will depend on how closely you follow your diet. How long you maintain weight loss will depend on how completely you adopt long-term lifestyle changes involving eating behavior and exercise.

Will I Regain My Weight after the BIB System Balloon Is Removed?

Because the balloon in the stomach creates a feeling of fullness, it acts as an aid to weight reduction and may help you to adhere to a prescribed diet. You will have a much greater chance of maintaining your weight loss after balloon removal if you maintain and improve the diet and behavior changes you made while using the balloon.

What Unpleasant Effects Are Possible with the BIB System?

It is very likely that the presence of the balloon in the stomach will cause nausea or vomiting for a few days after placement. Your physician can prescribe medication to alleviate these potential effects.

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, as stated earlier, your commitment to dietary and behavioral changes is a pivotal factor in the outcome.

There is also the chance that unhealthy, uncontrolled weight loss will occur and create adverse health consequences. Be sure to speak with your physician about this.

Are there Risks Associated with Using the BIB System?

As with all medical procedures, there is a risk of unforeseen, unknown or 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, either by

direct contact with the instruments used to place the balloon, by the balloon itself, or as a result of increased acid production by the stomach. Possible results are ulcer formation, pain, bleeding, and perforation. These complications could necessitate medical or surgical correction.

Should bacterial growth occur in the fluid that fills the balloon, release of contaminated fluid into the intestines when the balloon is punctured for removal may cause infection, fever, cramps and diarrhea.

Spontaneous deflation of the balloon is a complication that was described earlier in this booklet. Should this occur, the deflated balloon may pass through the bowel and be passed out of the body. However, it is possible for a deflated balloon to become lodged in the bowel and cause an obstruction. This is a serious complication, possibly requiring surgical removal of the balloon. If not treated immediately, it could result in death. Please contact your physician immediately if you have any indication that your balloon has deflated.

Of course, your physician is the most valuable person to whom to address all of your concerns. You are strongly encouraged to discuss all of your questions and expectations regarding the BIB System with your physician and to evaluate the benefits versus the possible risks before choosing to use the BIB System as a weight loss aid.

Best wishes on your efforts to achieve a healthier lifestyle!



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This Product is for Export Only

CAUTION: This device restricted to sale by or on the order of a physician.

The BioEnterics Intra-gastric Balloon System contains no latex or natural rubber materials.

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A Non-Surgical Aid in the Treatment of Obesity



BIB® System

BioEnterics® Intra-gastric Balloon (BIB®) System