



endura
Weight Loss Solutions

A TREATMENT GUIDE

BIB™

Intragastric Balloon System

Jumpstart your weight loss

The BIB™ System is one of the procedures that is part of Endura Weight Loss Solutions from Boston Scientific.

READY TO FIND A MORE SUPPORTIVE WAY TO MANAGE YOUR WEIGHT?

If you are one of the thousands of people who have tried different approaches to weight management without finding something that lasts, then you may need help of a different kind.

It's a fact that diets alone rarely change long-term eating habits.¹ Many people find themselves in a cycle of losing and gaining weight, as they move from one approach to another without the results they hoped for – the so-called “yo-yo” effect.

Others may resort to slimming drugs or diet suppressants, but even then unpleasant side effects can make it difficult to stay the course.

There is another option for people who want to lose weight but don't want or qualify for more drastic measures like surgery.²

Before deciding which procedure may be right for you, it's important to discuss available options with your physician.

Welcome to the BIB™ System



The BIB System is a tool that is designed to offer you the extra help you need to support healthy lifestyle changes.

The BIB System is a soft, saline filled silicone balloon that is placed in the stomach for up to six months. 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.

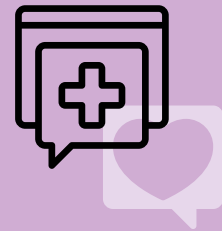
And because you will feel more satiated, you should find it easier to make the changes to your diet and lifestyle that will help you keep the weight off once the balloon is removed.

The BIB System does not involve surgery nor does it require long-term drug therapy. It is placed and removed during a 20 – 30 minute

“endoscopic” procedure, during which you will be mildly sedated.

Once the balloon is in place, your clinic should be able to provide you with dietary advice and support you in making gradual, sustainable changes to your eating and daily habits, to help you work towards your weight loss goals. Interested in finding out more? Then, please read on.

Each physician and patient should evaluate the risks associated with endoscopy and intragastric balloons and the possible benefits of a temporary treatment for weight loss prior to the use of the BIB System.



FINDING A HEALTHY WEIGHT RANGE FOR YOUR BODY

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.

The most common measurement used for indicating whether a person is overweight is **BODY MASS INDEX (BMI)**. You can work out your own BMI by using the following calculation: $\text{kg/m}^2 = \text{BMI}$.

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



BMI CLASSIFICATION³

18 – 24.9	Normal
25 – 29.9	Overweight
30 – 34.9	Obesity grade I
35 – 39.9	Obesity grade II
40 or above	Obesity grade III

SO IS THE BIB SYSTEM RIGHT FOR ME?

In addition, there are certain medical reasons for which you may not be eligible for treatment with the BIB System. These may include:

- Previous history of gastrointestinal surgery, or large hiatal hernia
- Unwillingness to adopt the dietary habits critical to the success of the therapy
- Drug or alcohol addiction
- Pregnancy or breast feeding
- Inflammatory disease of the gastrointestinal tract
- Upper gastrointestinal bleeding conditions or congenital anomalies of the gastrointestinal tract

* The BIB System is not approved for use in patients with a BMI lower than 30. This information is only a guide. Your doctor will be able to give you a much more accurate health assessment based on your BMI and other relevant factors and will ultimately determine whether you are suitable for treatment. 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.



If you have a BMI of 30* or more,
**the BIB System could be the
ideal solution for you.**

ABOUT THE PROCEDURE

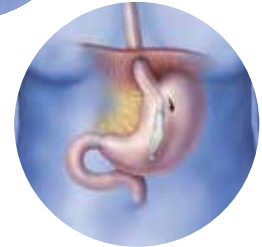
You will be lightly sedated whilst your clinician uses an endoscope to pass a deflated gastric balloon into your stomach. Once in place, the balloon is filled with saline solution via a small tube. The balloon valve seals when the tube is withdrawn.

The procedure usually takes 20–30 minutes. You will rest in the clinic for 1–2 hours for observation before being discharged.

For the first few days, as your stomach adjusts to the balloon, you will almost certainly feel uncomfortable. You may well experience nausea, bloating, diarrhoea and cramping.

These side-effects are typically experienced for the first few days and potentially up to about two weeks. If necessary, your clinician can prescribe suitable medication to manage them.

The balloon is removed in just a few steps. Whilst mildly sedated, an endoscope and some endoscopic instruments are used to deflate it before it's removed. You will be home within two or three hours. Most people need little or no time off work.



HOW MUCH WEIGHT CAN I EXPECT TO LOSE?

Many people experience meaningful weight loss during treatment.

The following weight loss results were achieved in published clinical studies using the BIB balloon.

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 diet and exercise. Your clinic should provide dietary and lifestyle advice to help you make the changes needed.

Large European Study, 2005

2,515 patients;
BMI loss was

4.9+/-12.7

kg/m² after 6 months.⁴

Brazilian Study, 2004

323 patients;
average weight loss
after 6 months:

15kg⁵

The BIB System is a tool to help you take control of your weight and give you the kick-start to a healthier lifestyle.

Studies show that patients who have undergone the BIB System procedure are more likely to maintain their weight loss over a longer period of time when compared to diet alone.⁶



Pre-procedure: Don't eat food or drink any liquids for 12 hours before the procedure. If you do, your clinician may not be able to proceed with your appointment.

GETTING PREPARED

If you're suitable for the BIB System and you want to proceed, your clinician will arrange a consultation before the procedure. You will be given specific dietary instructions to follow, including instructions if you take prescription medication. You can also discuss the procedures first hand.

For a basic overview, here's some general guidance.

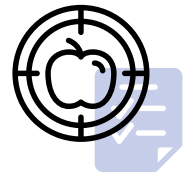
Since you will be on a liquid diet for **three days** after the procedure, you will be told to have certain food and drinks available at home. These may include:



- Juices
- Thin soups
- Milk
- Jellies

There are a few other things you need to plan for in advance:

- When you have your procedure, you will also need to be accompanied to and from the clinic. You will also need someone to stay with you for the first 24 hours.
- If you look after small children, arrange for childcare for at least 3 days.
- If you're staying in a hotel, please check in before your procedure and advise the clinic of your room number. We recommend that you have everything you need ready in the room before you are discharged from the clinic. Someone should stay with you for the first 24 hours.



ON THE DAY

- Remember not to have any food or drink for at least 12 hours before.
- Wear comfortable clothing and shoes.
- You will be given a prescription for any medicines to be used after the procedure.
- Once the procedure is over you will remain in the clinic for observation until your doctor discharges you.
- Your doctor will let you know if you need someone to take you home or to travel with you on public transport after your procedure.

FIRST STEPS

- Ensure you follow the advice provided by your clinician.
- Drink cold liquids in small amounts, beginning with a teaspoon, and slowly increase the amount of the liquid as you are able. If you drink large amounts there's a higher risk of nausea and vomiting.
- Rest. Don't do any physical activity for the first 24 hours.

Once you're back home

At this point you have taken the first important step in a journey that can change your life. The kick-start has begun and today is the start of a process that will help you retrain your appetite and achieve your weight loss goals. The first few days can be an adjustment period - your care team will guide you through it.

FIRST FEW DAYS

WEEK 1: LIQUID DIET

The first few days might be uncomfortable as the stomach gets used to the balloon. You may experience further nausea, vomiting, bloating, diarrhoea and cramping until your body adjusts. These conditions are typically experienced for the first few days and potentially up to about two weeks. Your physician will provide strict instructions for your hydration regime during this period. In the days that follow, it is critical that you drink plenty of water and avoid eating any solid foods.

ADJUSTING TO THE BIB™ SYSTEM

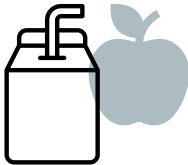
REMEMBER:

- Drink slowly, taking small sips
- Wait between the sips for a minute or two
- Don't drink more than 100 ml at once
- Wait for at least 10 minutes between drinks
- Your total fluid intake should not be **MORE THAN** 2.0 litres (8 cups) per day.



FLUIDS TO INCLUDE:

- Low-calorie, low-acid fruit juices
- Weak tea or coffee, preferably decaffeinated
- Clear broth or soup
- Low-calorie gelatins (e.g. fruit jelly)
- Low-fat yoghurt drinks
- Skimmed milk



You may want a 1-week supply of a meal replacement shake

to help you meet your calorie and protein needs
for the day (ask your clinician for more
information)

SECOND WEEK

WEEK 2: PURÉED, SOFT AND SOLID FOODS

Your stomach is starting to adapt to the intragastric balloon. So this is a time when it's important to "listen" to your body.

The transition from purée to solid foods should take approximately one week, but only progress when you can tolerate these foods comfortably. Always try to eat slowly, chewing food very well.

MAKING THE TRANSITION

FOR UP TO 3 DAYS: PURÉE FOODS

Once you're tolerating fluids well, you can start introducing purée foods into your meals. In many cases you will be able to eat the same foods the rest of your family is eating by puréeing them in a blender or food processor.

By this stage you should be incorporating protein into every meal. Don't worry if you aren't able to eat all that much, and remember to stop eating if you feel discomfort or pressure.



REMEMBER:

Don't forget to drink plenty of fluids all the time your balloon is in place.

FOR UP TO 4 DAYS: SOFT FOODS

This stage prepares you to return to solid foods. Again remember to eat slowly and chew your food very well. Choose foods that are low in fat, calories and carbohydrates. As you are learning to listen to your body during this transition, pay attention if you develop feelings of fullness, pressure or discomfort. These are signs that you should slow down or stop eating entirely in order to avoid discomfort or nausea by slowing down when you eat.

Examples of suitable soft foods:

- Bananas and other soft fruits
- Porridge/oatmeal
- Egg
- Yoghurt
- Cottage cheese
- Tinned tuna

SOLID FOODS

By now you're reaching the end of your dietary transition. You will have resumed your normal activities and begun retraining your appetite for a maintained and healthy weight loss. Here are some tips as you return to eating solids:

- Introduce solid foods one at a time.
- Try cooked foods first before hard/raw foods.
- Limit or try to avoid bread, pasta, rice and other starches. These foods may stick to the balloon, causing bad breath.
- Drink plenty of water and avoid eating and drinking at the same time; drink at least one glass ½ hour before each meal and two glasses ½ hour afterward to "rinse" the balloon.

To succeed with your managed weight loss, it's vitally important that you follow the nutritional plan and lifestyle changes your clinician outlined.

Whilst your BIB balloon is implanted, be careful to note 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 clinician know immediately.

REMEMBER:

- Use the **20/20 rule** when eating. Food should be chewed at least **20 times** and a meal should take **20 minutes** or more to consume.

NEXT SIX MONTHS

JUMPSTART HEALTHY WEIGHT LOSS

After the first two weeks, your body will have adjusted to the BIB balloon and you should be following a regular nutrition plan.

Your progress will depend on following your care plan and the ongoing support you receive. You may receive instructions from your clinician on your nutrition regime with calorie restrictions.

You may also have further appointments scheduled with a nutrition expert to monitor your progress. If so, make sure you attend every appointment.

The BIB System gives you a window of opportunity to adapt to the lifestyle changes you must make in order to maintain the weight and habits that help you feel your best.

The following guidelines will help you be more successful.



A MATTER OF BALANCE

Eating a balanced diet is essential. It simply means to include a variety of foods from all four food groups -vegetables and fruit, grain products, milk and alternatives, and meat and alternatives.

READ NUTRITIONAL LABELS

Nutritional Information labelling is mandatory on all pre-packaged food to help you, as a consumer, make informed decisions. It's important that you note not only the calorie count, but also the portion size being used on the label.

KEEP A FOOD DIARY

It's extremely useful to keep a food diary. Besides providing a useful record, it keeps you aware of the choices you make during the day. In this way, you can see each week when you're doing well – and when you need to make more effort to achieve your goals.

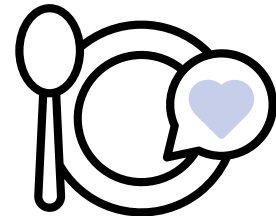
Other basic tips to adopting a healthier lifestyle:

- Select low-fat and low-calorie alternatives
- Limit your fat, sugar, alcohol and salt
- Increase your daily fibre intake
- Drink plenty of fluids, especially water

EXERCISE MATTERS

To lose the weight you want and keep it off, your body needs to become more active. It's the only way you will burn the calories you consume, and potentially improve your body's energy balance and metabolism. Don't panic: this doesn't mean running a daily marathon!

Even seemingly small changes – like taking the stairs instead of the lift – over time make a massive difference to your metabolic health and the daily calories your body burns.



MOVING ON

HAVING THE BIB BALLOON REMOVED

At six months (or earlier), the BIB balloon will be removed.

It's a 20 – 30 minute procedure, very similar to the one you experienced for placement.

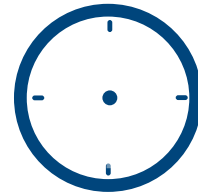
During the removal procedure, you will be slightly sedated.

Using an endoscope and small tube, your clinician will remove the saline from the balloon before retrieving the deflated balloon from your stomach.

Following removal of the BIB balloon your doctor will keep you in the clinic for a couple of hours following removal so that any sedative effects have a chance to wear off, and they can check that you are fit to go home.

IMPORTANT REMINDERS:

- No solid food 24 hours prior to the procedure.
- No liquids 12 hours prior to the procedure.
- Due to the effects of sedation, you may need to arrange for someone to drive you back home.



TAKING CONTROL – life after the BIB balloon.

You have made a bold decision to take control of your health, you took the first and most difficult steps to building confidence in your renewed health journey

Whilst in place, the BIB balloon has given you the extra support you need to achieve your weight loss goals and to ultimately look and feel better about yourself. Now, it's up to you to build on and sustain the changes you have made to the way you live.

Nourish your body in ways that help you feel energized and well. Remember that this is NOT a diet – it's a lifestyle change. Sustained success means staying committed to healthy eating, taking smaller portion sizes and pursuing an active lifestyle.

Remember, everyone has challenging days - it's part of progress.. Just remember to do better tomorrow. If you do overindulge, try not to panic. The most important thing is to understand why the lapse happened, and recognise the cause. Were you under pressure? Was it the social environment? Are you worried or depressed? If necessary, talk your feelings through with friends or family members. If you're concerned your healthy eating habits are deteriorating dramatically, consult your GP or a nutritional professional for advice.



KEEP ON TRACK

Your clinic may provide dietary and lifestyle advice to help you maintain your good habits. Be sure to follow the advice as closely as you can. Here are a few final tips to help you on your way.

If you notice you turn to food for comfort, try exploring other ways to support your emotional wellbeing

When things go wrong, it's often tempting to turn to food for comfort. Recognise the urge and try to redirect that urge by doing something kind for yourself, like a short walk or a relaxing activity. If you must eat, eat sensibly. You will be amazed at how much fresh vegetable and fruits can rejuvenate you and your spirit. Invest in a blender and you can make delicious, hunger-satisfying nutrient dense drinks.

Watch portion sizes

Healthy portion sizes keep the weight off. Stay conscious of your portion sizes, especially when others are serving food to you. If you find yourself with a serving that's too large, eat what you would normally then stop. Don't feel compelled to try and clear your plate. Eating from a smaller plate can help you manage how much you consume.

Stay busy and active

Exercising regularly means you will stay feeling good – both physically and mentally. Staying active not only burns calories and helps improve your cardiovascular health; it also shapes how you look. It's no coincidence that the compliments will just keep coming.

Water is your friend

Keep track of how much water you drink. You should still be drinking at least 8 glasses a day. Drinking water keeps you feeling full, and stops you from overindulging when it's time to eat.



GOOD LUCK!

Now that you have reached your goal you can begin to enjoy life to the full. You have successfully made significant changes to your diet and your lifestyle – it's something you can continue to build on.

Your success reflects your commitment and strength - the BIB System was just one of the tools that helped.



Indication for use

The BIB System is indicated for temporary use in weight-loss therapy for overweight patients with a Body Mass Index (BMI) of 30kg/m² or greater. The BIB System is to be used in conjunction with a long-term supervised diet and behaviour modification program designed to increase the possibility of long-term weight loss maintenance. The maximum placement period for the BIB System is 6 months, it must be removed at that time or earlier. Each physician and patient should evaluate the risks associated with endoscopy and intragastric balloons and the possible benefits of a temporary treatment for weight loss prior to use of the BIB System. Physicians have reported the concurrent use of medications which reduce acid formation or reduce acidity. Silicone elastomer is degraded by acid. Moderating the pH in the stomach should prolong the integrity of the BIB System. The materials used to fabricate this device have been tested according to ISO 10993, the International Standard for biological evaluation of medical devices. Longer periods of BIB System placement increase the risk of IGB deflation. The BIB System is for single use only. Removal of the IGB requires that it be punctured in situ to deflate, any subsequent reuse would result in the IGB deflating in the stomach. This could lead to possible bowel obstruction and may require surgery to remove.

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1. <https://pubmed.ncbi.nlm.nih.gov/33441193/>
2. Refer to IFU for Indications and Contraindications: www.IFU-BSCI.com
3. Yumuk et al.: European Guidelines for Obesity Management in Adults. Pag. 404
4. Genco A, Bruni T, Doldi SB et al. BioEnterics Intragastric Balloon: The Italian Experience with 2,515 Patients. *Obesity Surgery* 2005; 15:1161-1164.
5. Sallet JA, Marchesini JB, Paiva OS et al. Brazilian Multicentre Study of the Intragastric Balloon. *Obesity Surgery* 2004; 14:991-998.
6. Genco A, Balducci S, Bacchi V et al. Intragastric Balloon or Diet Alone? A Retrospective Evaluation. *Obes Surg* 2007; (DOI 10.1007/s11695-007-9383-9).

CAUTION: Content of this material is for Information Purposes only and does not constitute medical advice. BSC strongly recommends that you consult with your physician on all matters pertaining to your health or to address any questions. Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary. There are risks associated with all medical procedures. Please talk with your doctor about the risks and benefits associated with BIB System.

The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found at www.IFU-BSCI.com. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material is not intended for use in France.