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BIB™ Intragastric Balloon System

A Minimally Invasive Option to Jumpstart Patient Weight Loss

Start

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

endura
Weight Loss Solutions

The BIB™ Intragastric Balloon

A tried and tested, minimally invasive option for people living with obesity who may refuse or not qualify for surgical intervention.

The BIB System is a soft, silicone intragastric balloon, designed to induce weight loss by partially filling the stomach to help obese* patients achieve a feeling of satiety.

Feeling fuller, more quickly after small meals may help make it easier for these patients to change their dietary habits and ready to adopt a new, healthier lifestyle during the six months the balloon is in place.

* Patients with a BMI of ≥ 30kg/m^2.

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. Please refer to the full IFU for further information regarding the risks and benefits.

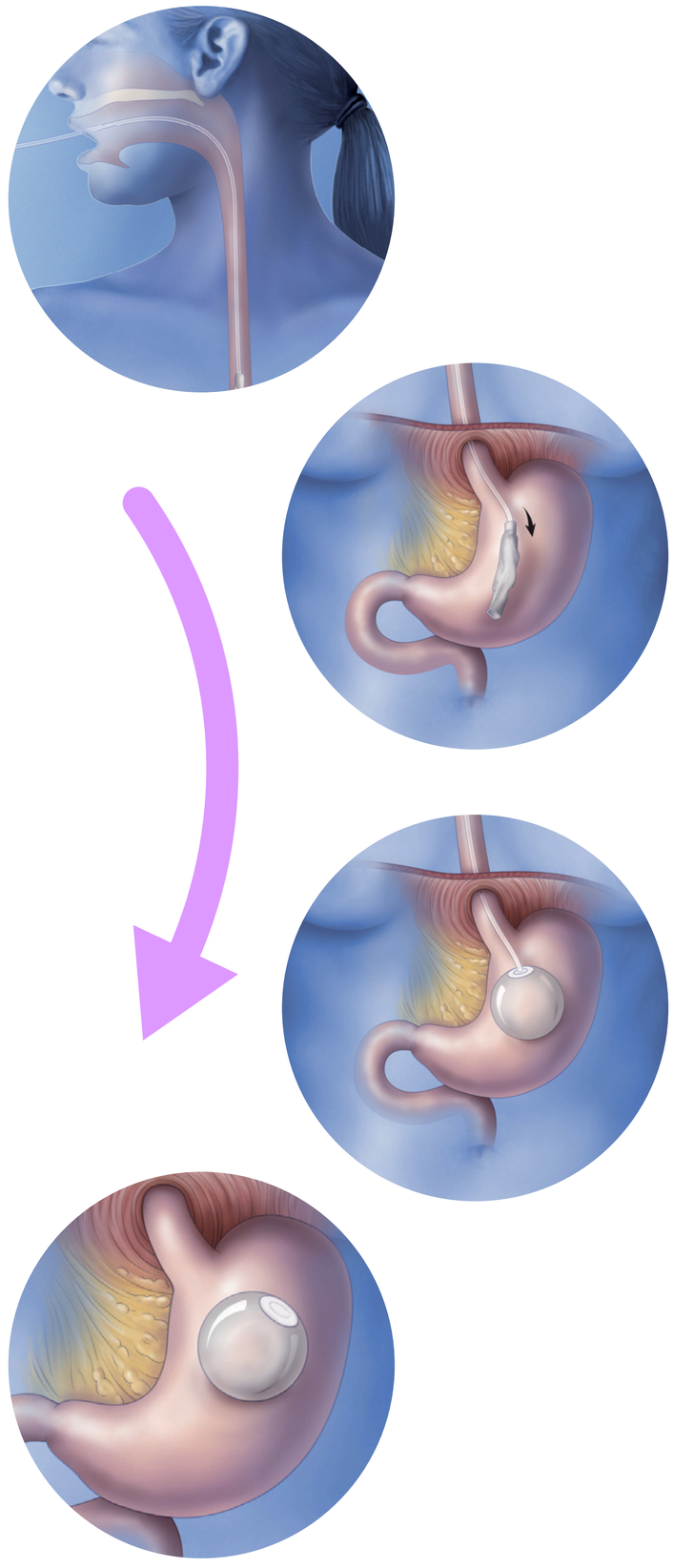
Weight loss for patients with obesity

- Diets alone rarely succeed in changing long-established eating habits.[1]
- The BIB™ System is a temporary option designed to help patients adjust to smaller portion sizes and adopt healthier eating habits.*
- Suitable for obese patients with a BMI of 30 or more who have significant health risks related to their obesity and who have failed to achieve and maintain weight loss with a supervised weight control programme alone.

* In conjunction with long-term supervised diet and behaviour modification programme.

Minimally invasive, effective weight loss procedure

- Smooth, silicone elastomer balloon.
- Endoscopically placed in the stomach and filled with saline.
- Soft, flexible catheter assembly with silicone sheath, filling connector and for easy insertion.
- Endoscopically deflated and removed with specially designed tools.
- Maximum placement period of up to 6 months.



The ideal intragastric balloon

In 1987 a group of leading experts from around the globe met to examine all aspects of patient treatment with the intragastric balloon. These 75 experts agreed the following characteristics of an ideal intragastric balloon, commonly known as the “Tarpon Springs Criteria“.[2]

Expert recommendations[2] Gastric balloons should:	The BIB™ System – Designed specifically to meet these criteria
Be effective at promoting weight loss	Yes
Wide fill volume range	Variable fill volume from 400 – 700cc to suit a wide range of patients
Be filled with liquid	Saline filled to induce the appropriate feeling of satiety for each patient
Contain a radiopaque marker that allows proper follow-up of the device if it deflates	A radiopaque valve allows location under X-ray
Be constructed of durable materials that do not leak, with smooth surface and low potential for causing ulcers and obstructions	Round, smooth, high quality silicone shell with proven durability and minimal irritation to the stomach wall for increased acceptability*[2,3]

Design reliability you can trust

* Recommended in combination with use of Proton Pump Inhibitor (PPI) treatment.

Clinical success backed by weight of evidence

In a 6 month, prospective, multicentre, non-controlled study, 323 patients showed significant ($p<0.001$) reductions in the following outcomes compared to baseline:

85%
SUCCESSFUL WEIGHT LOSS*

* Success was defined as > 20 % excess weight loss (EWL).

MEAN WEIGHT LOSS	MEAN REDUCTION IN BODY MASS INDEX (BMI)	PERCENTAGE EXCESS WEIGHT LOSS (EWL)
- 15.2 kg (± 10.5 kg)	- 5.3 kg/m² (± 3.4 kg/m²)	48.3 % (± 28.1 %)

Similar results were found in a large European retrospective study involving 2,515 obese patients.[4]

Results 6 months after the BIB balloon placement:

MEAN REDUCTION IN BMI	PERCENTAGE EWL
- 4.9 kg/m²	33.9%

The BIB™ System delivers considerable weight loss compared to diet alone[1]

A retrospective study compared the outcomes of the BIB System placement with diet regimen alone in 130 overweight patients with similar BMIs at baseline over an 18-month period.

Weight loss comparison at 6 and 24 month follow-up[1]

Results	6 months		24 months	
	* The BIB System	Diet	** The BIB System	Diet
Weight loss (kg)	16.7 (± 4.7)	6.6 (± 2.6)	11.2 (± 4.9)	1.5 (± 2.9)
BMI reduction	6.1 (± 4.3)	2.5 (± 2.1)	3.9 (± 3.1)	0.7 (± 0.8)
%EWL	33.9 (± 18.1)	24.3 (± 17.0)	21.3 (± 19.7)	2.9 (± 3.1)

* At time of removal ** 18 months post-removal

- Significantly better weight loss results were observed in patients treated with the BIB balloon compared with the diet-treated controls at removal ($p<0.01$) and at 18 months post-removal ($p<0.001$).
- Furthermore, the dropout rate was significantly lower in patients treated with the BIB System (1 % vs 18 % diet-treated patients, $p<0.001$).

This study also indicated that the influence of the BIB System treatment on patients' behaviour is at least partially maintained after removal of device.

Well tolerated for the majority of patients[3,5]

Most patients adjust to the BIB™ System within a few days.

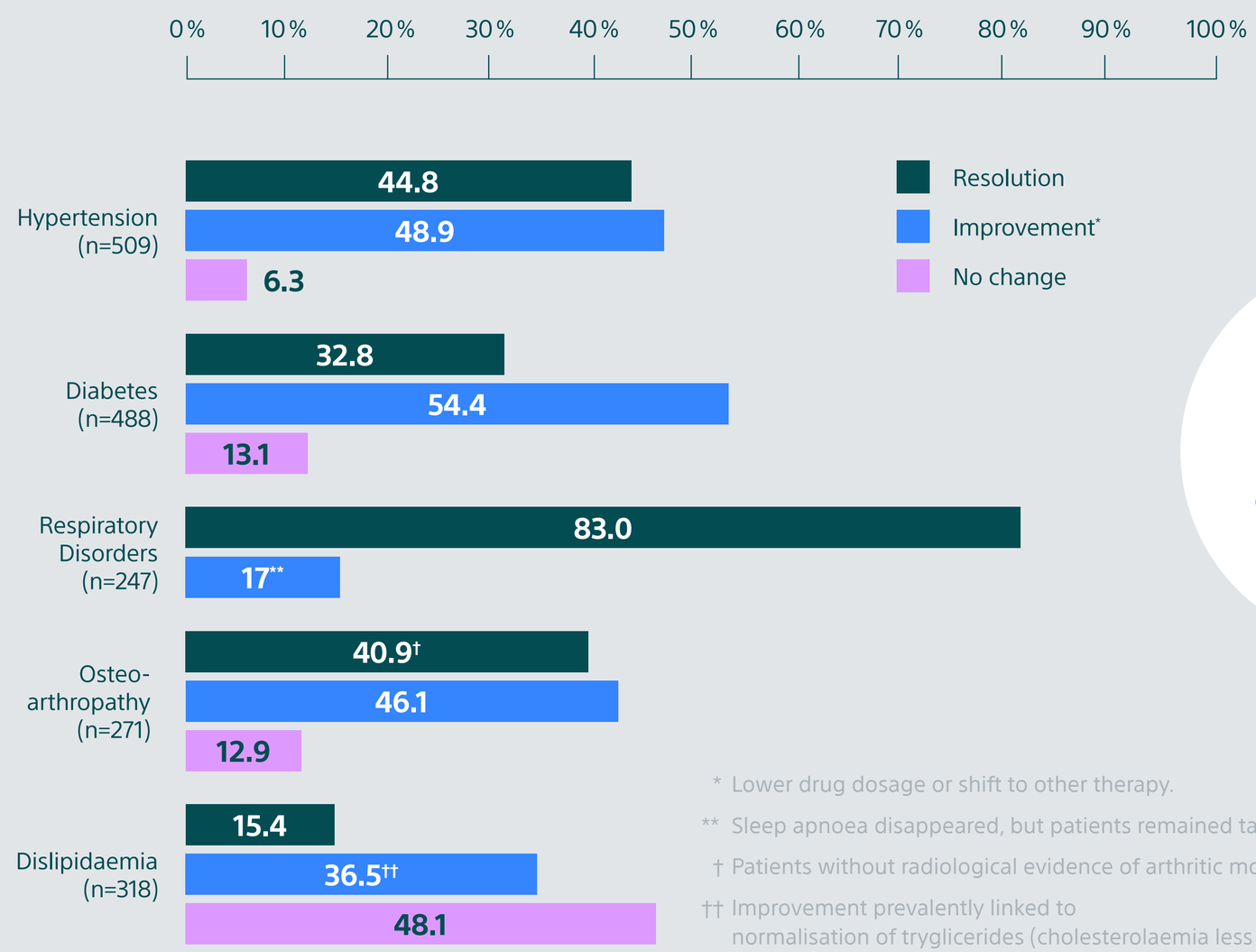
- Across the treatment period, the BIB balloon was generally well tolerated. Common adverse effects include nausea, vomiting and belching within the first 3–5 days after placement, the intensity of which can vary from patient to patient, usually disappearing within a few days.[6]
- Clinicians report that patients come to regard the BIB balloon in a very positive manner once transient side effects have subsided, judging it “good”, “very good” or “excellent”.[6]

Minor complications may include: Reflux oesophagitis (controllable with PPI therapy) and transient symptomatic gastric stasis.

Contraindications include: Patients who have had previous gastrointestinal surgery, psychiatric disorders, noncooperative patients, alcoholics and drug addicts. Pathology that includes large hiatus hernia, inflammatory disease of the gastrointestinaltract including oesophagitis and gastric ulceration.

Please refer to the full IFU for further information at www.IFU-BSCI.com.

A large european study also demonstrated a satisfactory improvement on co-morbidities[4]



89%

CO-MORBIDITIES IMPROVED[4]

* Lower drug dosage or shift to other therapy.

** Sleep apnoea disappeared, but patients remained tachypneic after physical activity.

† Patients without radiological evidence of arthritic modification.

†† Improvement prevalently linked to normalisation of tryglicerides (cholesterolaemia less influenced).

Additonal Advantages of the BIB™ System

Weight loss for patients with obesity
The greater incidence of obesity is becoming a daily challenge in surgical practice. Morbidly obese patients are at increased risk of post-operative complications.[7]

"The BIB System has played an essential role in the preoperative treatment of morbidly obese patients who are scheduled to undergo bariatric or other elective surgery by minimizing morbidity and mortality risks".[1]

"Laparoscopic sleeve gastrectomy and Bio-Enterics intragastric balloon are two valid options for producing weight loss as a first-step procedure. LSG has all the related risks of general anesthesia, laparoscopic surgery, and digestive anastomosis, whereas BIB presents a very low rate of minor complications, such as psychological intolerance. For all these reasons, at this time, BIB is considered a better option than LSG as a first-step procedure in the short term (12 months)."[8]

Comparable short-term weight loss option than Laparoscopic Sleeve Gastrectomy (LSG)[8]
In a study that compared the efficacy of LSG (n=40) with the BIB System intragastric balloon (n=80), it was found that both procedures offered:

- Comparable weight loss at 6-month follow-up.
- Comparable reductions in co-morbidities at 6-month follow-up.

However,

- LSG is irreversible and carries all related risks of anaesthesia, laparoscopic surgery and digestive anastamosis.
- The BIB System presents a very low rate of minor complications and is fully reversible.

The BIB™ System – Help your patients jumpstart healthy weight loss

- Patients achieve greater weight loss with the BIB System than with diet alone.[1,7]
- Large-scale studies support excess weight loss between 34 and 48%.[6,4]
- Simple endoscopic placement and removal
- Established safety profile[4] with over 20 years proven experience.
- Shown to reduce co-morbidities.[4]
- Proven role in reducing the risks of elective surgery.[9]

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6. Sallet JA, Marchesini JB, Paiva OS et al. Brazilian Multicentre Study of the Intragastric Balloon. Obesity Surgery 2004; 14:991-998.
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CAUTION: 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.

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