



**Australian Government**  
**Department of Health and Ageing**



## Horizon Scanning Technology Prioritising Summary

BioEnterics® Intra-gastric Balloon for obesity

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**Australian  
Safety  
and Efficacy  
Register  
of New  
Interventional  
Procedures -  
Surgical**



**Royal Australasian  
College of Surgeons**

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The production of this Horizon scanning prioritising summary was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from health departments in all states and territories, the Australia and New Zealand governments; MSAC and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

This Horizon scanning prioritising summary was prepared by staff from the Australian safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S).

# Horizon Scanning Technology Prioritising Summary

## Name of Technology:

BioEnterics® Intragastric Balloon (INAMED Health).

## Purpose and Target Group:

The BioEnterics® Intragastric Balloon (BIB® System) is a smooth, spherical, saline-filled, silicone elastomer that is endoscopically inserted into the stomach via the oesophagus. It limits food consumption and promotes weight loss by inducing a feeling of satiety.

## Stage of Development (in Australia):

- Experimental
- Investigational
- Nearly established
- Established
- Established but changed indication or modification of technique
- Should be taken out of use

The BioEnterics® Intragastric Balloon is registered in the Australian Register of Therapeutic Goods (ARTG number: 106802).

## International Utilisation:

COUNTRY	LEVEL OF USE		
	Trials underway	Limited use	Widely diffused
United States		✓	
Australia		✓	

## Impact Summary:

### *Background*

Obesity is a chronic disease of excess body fat storage and is defined by the World Health Organization as a body mass index (BMI) of  $\geq 30 \text{ kg/m}^2$  (Australian Institute of Health and Welfare 2004). Obesity is the leading risk factor for Type II diabetes, stroke, gout, stress incontinence, cancer (especially breast, endometrial and colon cancer) and sleep apnoea, as well as numerous cardiovascular diseases (Uwaifo and Arioglu 2004).

The initial treatment for obesity involves a calorie-restricted diet, an exercise regime and behavioural modifications. However, some patients are unable to achieve adequate weight loss (5% to 10% weight loss in three to six months) despite considerable effort.

In such cases, patients are usually prescribed pharmacological treatment such as phentermine, diethylpropion, phendimetrazine, benzphetamine and orlistat (Xenical). Morbidly obese patients (BMI > 40 kg/m<sup>2</sup>) are usually considered for surgery because of their limited success with the aforementioned treatments. Procedures such as gastric banding, Roux-en-Y gastric bypass and biliopancreatic diversion can achieve rapid, maintainable weight loss in morbidly obese patients (Uwaifo and Arioglu 2004). However, there exists an intermediate group of patients who respond poorly to non-surgical treatments but are not eligible for surgery. For these patients, the use of an intragastric balloon is an attractive option. The BIB System comprises an inert, non-toxic silicone elastomer that is resistant to gastric acid. In the collapsed state, it is small and flexible but expands to a spherical shape when filled with saline. Its volume is regulated (400 mL to 800 mL) with a radiopaque self-sealing valve. The balloon is inserted into the stomach via the oesophagus using a placement catheter, and a fill tube is used to inflate the balloon once it is in position (Mathus-Vliegen *et al.* 2005). INAMED claims that the inflated balloon induces the feeling of satiety, thereby enabling the recipients to better control their diet and achieve weight loss.

### ***Clinical Need and Burden of Disease***

Approximately 100 million adults in the United States are overweight or obese. While adult obesity in itself is significant (35% of women and 31% of men older than 19 years are obese/overweight), the increasing prevalence of obesity among children is a cause for great concern (20% to 25% of children in the United States are obese/overweight). An estimated US\$100 million is spent annually on the management of obesity in the United States (Uwaifo and Arioglu 2004).

The Australian Diabetes, Obesity and Lifestyle Study reports that over 7 million adult Australians (≥ 25 years old) are overweight, and 21% of them (approximately 2 million) are obese. In 1995, 21% of boys and 23% of girls aged between 2 and 17 years were overweight or obese, and the proportion continues to increase (Australian Institute of Health and Welfare 2004). It has been estimated that obesity accounted for over 4% of the total burden of disease in Australia in 1996 (Mathers *et al.* 1999).

In New Zealand, one in five adults (20.9%) are obese with the prevalence of weight gain increasing with age until the 55-64 years age group (A Portrait of Health 2004).

### ***Estimated Speed and Geographic and Practitioner Use Patterns of Diffusion in the Health System***

The BIB System has been approved by the Therapeutic Goods Administration for use in Australia. Although this procedure is currently offered in Australia, it appears to be rarely used compared to other obesity treatments such as the Lap-Band® procedure.

## ***Existing Comparators***

- Gastric bypass (Roux-en-Y procedure)
- Laparoscopic adjustable gastric banding (BioEnterics® LAP-BAND® System)
- Biliopancreatic diversion
- Vertical banded gastroplasty

## ***Estimated Cost Impact***

The cost of the BIB System in Australia was not revealed in our searches. The Medicare Benefits Schedule does not list any reimbursements for the use of intragastric balloons for the treatment of obesity. However, the reimbursement fee for gastric reduction or gastroplasty for morbid obesity is AU\$735.25 (Item number: 30511), gastric bypass for morbid obesity is AU\$904.80 (Item number: 30512), while surgical reversal of morbid obesity by any method which applies to item 30511 and 30512 (Item number: 30514) is \$1332.10 (Medicare Australia 2005). Other reimbursement fees include the repair, revision or replacement of a long-term implanted reservoir associated with adjustable gastric banding (Item number: 31441) which is \$217.80 and accessing of long-term implanted reservoirs for adding or removing fluid is \$84.70 (Item number: 14215).

From July 2004 to June 2005, the number of claims for the above mentioned item numbers are 4349 (Item number: 30511), 186 (Item number: 30512), 493 (Item number: 30514), 424 (Item number: 31441) and 31,122 (Item number: 14215).

## ***Efficacy and Safety Issues***

### **List of Studies Found**

Total number of studies	9
Randomised controlled trials	1
Non-randomised comparative studies	1
Case series studies	7

The studies included in this summary are highlighted in bold in the reference list.

Safety and efficacy data from one randomised controlled trial, one non-randomised comparative study and seven case series studies represent the main body of evidence available for this device.

The double-blind randomised controlled trial conducted by Mathus-Vliegen *et al.* (2005) compared a sham treatment group (n = 21) to patients receiving the BIB System (n = 12) over a three month period (mean BMI for all patients = 43.3 kg/m<sup>2</sup>). Patients from both groups who achieved a preset weight loss were then selected to receive an additional nine months' of balloon treatment comprising three treatments of three months' duration. Intention-to-treat analysis revealed that both the sham- and balloon-treated patients achieved a similar mean weight loss of 11.2 kg and 12.9 kg, respectively, during the first three months. Between three and six months, the patients treated with a balloon lost 3.9 kg (3.5%) (the second BIB treatment period), while the sham treatment group lost 8.8 kg (7.9%) (the first three months of BIB treatment). After six months of treatment, there was no detectable difference between the sham/BIB and BIB/BIB groups in terms of overall weight loss (20 kg (16.1%) and 16.7 kg (13.4%), respectively). After one year of treatment, the overall mean weight loss achieved was 21.3 kg (17.1%) in all patients. One year after balloon removal, an overall weight loss of 12.6 kg (9.9%) was maintained, with 47% of patients achieving more than 10% weight loss. Patients who completed the study per protocol (n = 33) recorded an overall weight loss of 25.6 kg (20.5%) after one year of treatment, and 88% of patients lost between 10% and 15% of their initial weight. A mean weight loss of 14.6 kg (11.4%) was maintained one year after balloon removal. Weight loss of at least 10% and 15% was sustained over two years in 55% and 39% of patients, respectively (Mathus-Vliegen *et al.* 2005).

One non-randomised comparative study (Milone *et al.* 2005) compared the BIB System to laparoscopic sleeve gastrectomy (LSG) as an initial weight loss treatment for super obese patients (BMI ≥ 50 kg/m<sup>2</sup>). Both patient groups were evaluated after six months of treatment. The mean weight loss for patients who received balloon or LSG treatment was 22.3 kg and 45.5 kg, respectively, while the percent excess weight loss (EWL) was 24% and 35%, respectively. The mean BMI of the balloon-treated patients decreased from 59 kg/m<sup>2</sup> to 51 kg/m<sup>2</sup>, while that of the LSG patients decreased from 69 kg/m<sup>2</sup> to 53 kg/m<sup>2</sup>. Overall, LSG patients achieved faster and greater weight loss than the BIB patients in this study. Four BIB patients (7%) did not tolerate the treatment and required balloon removal, whereas complications were non-existent for LSG.

The retrospective case series study by Genco *et al.* (2005) analysed the efficacy of BIB in 2515 patients (mean BMI = 44.4 kg/m<sup>2</sup>) after six months of treatment. The mean BMI at the end of treatment was 35.4 kg/m<sup>2</sup> (33.9% mean EWL). In addition to this, Genco *et al.* (2005) analysed the effect of BIB-induced weight loss on the prevalence of obesity related co-morbidities. A total of 1394/2471 patients (56.4%) were diagnosed with one or more co-morbidities (hypertension, diabetes, respiratory disorders, osteoarthropathy, dyslipidaemia and others) before treatment. Co-morbidities were resolved in 617/1394 patients (44.3%), while improvement (decrease in drug dosage, shift in therapy) was

recorded in 625/1394 patients (44.8%). In 152/1394 patients (10.9%), weight loss was not associated with any change in co-morbidities.

Doldi *et al.* (2002) treated 281 patients (mean BMI = 41.8 kg/m<sup>2</sup>) with BIB and reported that all patients experienced weight loss at four months' follow-up (mean weight loss = 14 kg). Obese patients (BMI < 40 kg/m<sup>2</sup>) achieved a mean weight loss of 12 kg, while morbidly obese patients (BMI > 40 kg/m<sup>2</sup>) achieved a mean loss of 17 kg. Sixty five patients remained on BIB treatment for six months and achieved a mean weight loss of 12 kg, with obese and morbidly obese patients achieving a mean weight loss of 9 kg and 13 kg, respectively (mean BMI reduction = 4.1 kg/m<sup>2</sup>). Similar results were obtained by Totté *et al.* (2001), where 69 patients achieved a mean weight loss of 15.7 kg (50.8% mean EWL) at six months' follow-up. Doldi *et al.* (2002) also evaluated the efficacy of BIB plus diet restriction versus diet restriction alone and found that the combination of BIB plus diet restriction resulted in greater weight loss over a shorter period of time, compared to diet restriction alone. However, women in the BIB plus diet restriction group started regaining weight (mean increase of 4.3 kg) at 12 months, whereas men in this group gained a mean of 10 kg after 18 months. In contrast, patients treated with diet restriction alone were better able to maintain weight loss (mean increase of 0.8 kg among men and 3.0 kg in women after 18 months).

Roman *et al.* (2004) achieved a more modest mean weight loss of 9.5 kg in 163 patients who were treated with BIB for four to six months. The overall mean EWL was 38.1%. The results for patients treated with a 600 mL balloon (n = 32) were significantly better than for patients receiving a 500 mL balloon (n = 131) (mean 12.9 kg and 8.6 kg loss, respectively; P < 0.002). Twenty patients (12.3%) did not achieve any weight loss.

In 31 patients with a BMI < 40 kg/m<sup>2</sup>, Al-Momen *et al.* (2005) reported a mean weight loss of 13 kg after six months, while a considerably greater mean weight loss of 33 kg was achieved in seven super obese patients (BMI > 50). Similarly, Loffredo *et al.* (2001) reported a mean weight loss of 14.3 kg (23.5% mean EWL) in 64 moderately or severely obese patients who were treated with BIB for three to six months.

Herve *et al.* (2005) reported that 100 patients had achieved an overall mean weight loss of 12 kg (39.8% mean EWL) when the BIB System was removed after six months. Pre-obese patients (BMI 25 kg/m<sup>2</sup> to 29.9 kg/m<sup>2</sup>) experienced a mean weight loss of 7.1 kg (43.4% mean EWL); patients with BMI 30 kg/m<sup>2</sup> to 34.9 kg/m<sup>2</sup> achieved a mean weight loss of 11.7 kg (41.2% mean EWL); and patients with BMI 35 kg/m<sup>2</sup> to 39.9 kg/m<sup>2</sup> attained a mean weight loss of 16.6 kg (42.4% mean EWL). In morbidly obese patients (BMI > 40 kg/m<sup>2</sup>), the mean weight loss was 17.2 kg (25.9% mean EWL). Twelve months after BIB removal, the mean overall weight loss was 8.6 kg (26.8% mean EWL).

The mean weight loss was 7.8 kg (29.9% mean EWL) for patients with BMI 25 kg/m<sup>2</sup> to 29.9 kg/m<sup>2</sup>; 7.8 kg (27.1% mean EWL) for patients with BMI 30 kg/m<sup>2</sup> to 34.9 kg/m<sup>2</sup>; 11.1 kg (25.4% mean EWL) for patients with BMI 35 kg/m<sup>2</sup> to 39.9 kg/m<sup>2</sup>; and 15.7 kg (20.4% mean EWL) for patients with BMI > 40 kg/m<sup>2</sup> (Herve *et al.* 2005). When EWL was compared between the time points of BIB removal and 12 months post-removal, the overall results indicated that patients were slowly gaining weight. At 12 months post-removal, 44 patients had not achieved 20% EWL (unsatisfactory), compared to 26 patients at BIB removal; 34 patients had achieved 20% to 50% EWL (good), compared to 40 patients at BIB removal; and 22 patients had achieved more than 50% EWL, compared to 34 patients at BIB removal. Overall, sustainable weight loss was achieved in 56% of patients 12 months after BIB removal (Herve *et al.* 2005).

Lofreddo *et al.* (2001) reported a mean weight loss of 14.3 kg (22.1% mean EWL) in a cohort of 64 patients treated for three to six months with BIB (mean initial body weight was 113.4 kg; BMI = 41.2 kg/m<sup>2</sup>). Eighteen patients (28%) achieved good results (mean weight loss = 15.2 kg) and decided to attempt further weight loss using the LAP-BAND® System. Another 34 patients achieved good weight loss (mean 16.5 kg) but did not opt for further treatment. Four months after BIB removal, 28 patients from this group gained a mean of 5.5 kg. After 1.5 years, four patients regained all the lost weight. Two patients from this cohort managed to maintain 75% EWL two years post-BIB removal. Twelve (18.7%) patients failed to maintain their weight after the initial weight loss due to poor compliance, excessive eating or psychological problems.

Recipients of the BIB System often experience nausea and vomiting, especially during the first few weeks of treatment. Herve *et al.* (2005) reported 78 (78%) cases of nausea and 66 (66%) cases of vomiting during the hospitalisation period, a statistic that was similar to Al-Momen *et al.* (2005) where 34 patients (77.2%) experienced vomiting during the first week after balloon insertion. In Roman *et al.* (2004), 90% of patients were affected by vomiting during the first week of BIB treatment, which resulted in nine cases (5.1%) of clinical dehydration, but the incidence of vomiting dropped to 18.2% after the first week. In addition, asymptomatic hyperkalaemia occurred in 15 patients and 2 patients developed functional renal insufficiency (Roman *et al.* 2004). Severe nausea, vomiting and abdominal cramps may also indicate patient intolerance to BIB. Mathus-Vliegen *et al.* (2005) reported three patients who persistently suffered from these conditions and required balloon removal. Balloon intolerance caused early removal of BIB in 4.3% of patients in Totté *et al.* (2001); 7.7% of patients in Doldi *et al.* (2002); 8.5% of patients in Roman *et al.* (2004); 5% of patients in Herve *et al.* (2005); and 13.6% in Al-Momen *et al.* (2005).

Other undesirable side effects associated with the use of BIB include oesophagitis, hiatal hernia, oesophageal erosion, heartburn (gastric reflux), diarrhoea, constipation, gastric

perforation and gastric erosion. Most of these conditions are relatively rare and are easily addressed with pharmacological or medical treatment. Although the risk of gastric perforation is low, it is nonetheless a serious complication that requires immediate treatment. Totté *et al.* (2001) treated two patients (2.8%) for gastric perforations, while Al-Momen *et al.* (2005) reported one (2.2%) case of perforation. Genco *et al.* (2005) reported five (0.19%) cases of gastric perforation; three patients were successfully treated using laparoscopic repair but two patients died.

There is also the possibility of device rupture and migration with the BIB System. Three balloons (2.3%) deflated spontaneously in one cohort (Mathus-Vliegen *et al.* 2005); one was removed endoscopically while the other two passed uneventfully through the digestive tract. Doldi *et al.* (2002) reported that five balloons deflated without the patient knowing and were passed uneventfully, whereas Herve *et al.* (2005) discovered two defective valves and one immediate balloon deflation during insertion. Roman *et al.* (2004) reported one case of partial bowel obstruction due to deflation and migration of the balloon, as well as one case of complete small bowel obstruction 14 months after placement. Meanwhile, Loffredo *et al.* (2001) recorded 15 (23.4%) spontaneous deflations, a relatively high rate compared to other studies. Genco *et al.* (2005) reported that 19 patients (0.76%) experienced gastric obstruction within the first week of treatment, while balloon rupture occurred in 9 patients (0.36%).

### ***Ethical Issues***

No issues were identified from the retrieved material.

### ***Cultural or Religious Considerations***

No issues were identified from the retrieved material.

### ***Other Issues***

No issues were identified from the retrieved material.

### **Recommendation:**

In morbidly obese patients, the BioEnterics® IntraGastric Balloon is capable of safely inducing substantial weight loss in the early stages of treatment. Long-term results (2 years, 1 year balloon treatment and 1 year balloon-free follow-up) indicate that around 50% of patients are able to maintain at least 10% weight loss after the treatment (Mathus-Vliegen *et al.* 2005). However, the efficacy of BIB as an initial weight loss treatment for super obese patients ( $BMI \geq 50 \text{ kg/m}^2$ ) before they undergo the Lap-Band® procedure needs further scrutiny as LSG appears to be more effective (Milone *et*

al. 2005). Based on the evidence, this procedure is not recommended for clinical practice as there are more efficacious alternatives.

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| <input type="checkbox"/> Horizon Scanning Report | <input type="checkbox"/> Full Health Technology Assessment |
| <input type="checkbox"/> Monitor                 | <input checked="" type="checkbox"/> Archive                |

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**Search Criteria:**

A search of MEDLINE, PubMed, *The Cochrane Library*, the Current Controlled Trials metaRegister, the UK National Research Register, the International Network for Agencies for Health Technology Assessments, relevant online journals and the Internet was conducted in August 2005.

Search terms used were: 'Bioenterics Intra-gastric Balloon', 'Bioenterics', 'Intra-gastric balloon', 'BIB INAMED', and 'INAMED balloon'.

on behalf of the Medical Services Advisory Committee (MSAC) and the Australian Health Ministers' Advisory Council (AHMAC).