

# News Release



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## **LAP-BAND™ is first obesity intervention device in Europe indicated for weight loss that improves or leads to remission of type 2 diabetes**

### ***Medical experts call for greater consideration of gastric banding for obese people with type 2 diabetes***

**Embargoed until 00.01 on June 26th 2009, London:** – Allergan’s LAP-BAND™ AP System for obesity intervention has become the first device to receive official European approval for weight loss that leads to improvement or remission of type 2 diabetes. Type 2 diabetes has reached pandemic proportions<sup>i</sup> and the risk of developing the disease has increased up to 10 times in people who are obese. Obesity is defined as having a Body Mass Index of 30 or greater. Alarming, the United Kingdom has the fastest growing rate of obesity in the developed world.<sup>ii</sup>

Obesity and type 2 diabetes are likely to be the greatest public health problems of the next decade.<sup>iii</sup> In the United Kingdom, it is estimated that the number of obese people with type 2 diabetes has increased by 1 million over the past 5 years.<sup>ii</sup> Recent estimates are that 10 per cent of the National Health Service (NHS) spending goes on diabetes. This equates to £9 billion a year - that’s £1 million an hour.<sup>iv</sup> Current lifestyle and pharmacological approaches are only modestly successful in causing sustained weight loss in obese people with type 2 diabetes.<sup>v,vi,vii</sup>

“Type 2 diabetes is becoming an increasing problem as the prevalence of severe or morbid obesity in the population rises. The proven success of gastric banding procedures in these patients is timely and provides us with a powerful alternative to tackle the morbidity and mortality associated with diabetes. Diabetes was coined by Shape Up America to define the direct correlation between diabetes and obesity” said Dr Jonathan Pinkney, Consultant Senior Lecturer and Diabetologist. “The gastric banding procedure is a highly effective option for selected obese patients who are failing to

reduce their weight through traditional weight-reduction methods. The recognition of a device such as the LAP-BAND™ AP System by the European health authorities is an important advance for the medical community and obese patients in our efforts to effectively manage type 2 diabetes.”

Gastric banding procedures are a well-established method of achieving significant and sustained weight loss. In 2006, the National Institute of Clinical Excellence recommended bariatric surgery such as gastric banding as a treatment option for people with obesity whose Body Mass Index (BMI) is between 35kg/m<sup>2</sup> and 40kg/m<sup>2</sup> and have other significant diseases such as type 2 diabetes or high blood pressure, or for those with a BMI greater than 40kg/m<sup>2</sup>.<sup>viii</sup>

According to Mr Paul Super, bariatric surgeon specialized in obesity intervention, “There are many people who could benefit from gastric banding procedures but are currently not being referred. Given this recent development, doctors who manage obese patients with type 2 diabetes should seriously consider gastric banding as an option to help these patients get their weight down and under control. Significantly, the expanded label for the LAP-BAND™ AP System recognises its effectiveness beyond weight loss intervention to include an important role in the resolution or management of type 2 diabetes. This important label change endorses the evidence that gastric banding could reduce the burden of the management of type 2 diabetes and could result in significant cost savings to the National Health Service.”

The recent decision by TUV SUD – a European Union notified body responsible for the certification of medical devices – recognizes the LAP-BAND™ AP System as the first obesity intervention device in Europe officially approved for weight loss leading to improvement or remission of type 2 diabetes. Specifically, the LAP-BAND™ AP System Directions For Use (DFU) or label now states that weight loss associated with the LAP-BAND™ AP System has been shown to improve or lead to remission of type 2 diabetes.

The evidence leading to the expanded product label comes from a landmark two year randomised controlled clinical study which shows that patients who lost weight with the LAP-BAND™ AP System were over 5 times more likely to achieve remission of type 2 diabetes than those receiving conventional diabetes therapy (73% vs 13%). This is the first randomised controlled study to compare surgically induced weight loss with

conventional therapy for management of type 2 diabetes in obese patients. These results confirm the findings of previous observational studies.<sup>ix</sup>

### **About Allergan, Inc.**

Founded in 1950, Allergan, Inc., with headquarters in Irvine, California, is a multi-specialty health care company that discovers, develops and commercializes innovative pharmaceuticals, biologics and medical devices that enable people to live life to its greatest potential - to see more clearly, move more freely, express themselves more fully. The Company employs approximately 8,000 people worldwide and operates state-of-the-art R&D facilities and world-class manufacturing plants. In addition to its discovery-to-development research organization, Allergan has global marketing and sales capabilities with a presence in more than 100 countries.

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### **Notes to Editors**

What is the LAP-BAND™ AP System?

The LAP-BAND™AP System is a tool to aid long-term weight loss and reduce the health risks associated with severe and morbid obesity. Unlike gastric by-pass, it does not involve stomach cutting, stapling or intestinal re-routing and is reversible.<sup>x,xi,xii</sup>

Using laparoscopic (key hole) techniques, an inflatable silicone band is placed around the top portion of the patient's stomach, creating a small pouch. The LAP-BAND™AP System works by reducing a person's stomach capacity and creating an earlier feeling of satiety, or fullness. The LAP-BAND™AP System is adjustable, which means that the inflatable band can be tightened or loosened, helping the patient achieve a level of satiety while maintaining a healthy diet.

## Biographies

Dr Jonathan Pinkney is Consultant Senior Lecturer and Diabetologist, Peninsula College of Medicine and Dentistry, Universities of Exeter and Plymouth

Mr Paul Super is Consultant Upper GI Surgeon, Heart of England NHS Foundation Trust, Birmingham. Mr Super fits gastric bands in an average of 20 patients each week in his NHS and private practices.

## Resources

For more information on weight loss visit: [www.weightloss4diabetes.co.uk](http://www.weightloss4diabetes.co.uk)

## References

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- <sup>i</sup> Diabetes - the policy puzzle: is Europe making progress? FEND & IDF Europe report, second edition. 2008
- <sup>ii</sup> Diabetes in the UK 2004. A report from Diabetes UK. October 2004
- <sup>iii</sup> Zimmet P, Alberti KG, Shaw J. Global and societal implications of the diabetes epidemic. *Nature*. 2001;414(6865):782-787
- <sup>iv</sup> Diabetes . Beware the silent assassin. A report from Diabetes UK. October 2008
- <sup>v</sup> Khan MA, St Peter JV, Breen GA, Hartley GG, Vessey JT. Diabetes disease stage predicts weight loss outcomes with long-term appetite suppressants. *Obes Res*.2000;8(1):43-48
- <sup>vi</sup> Zimmet P, Shaw J, Alberti KG. Preventing type 2 diabetes and the dysmetabolic syndrome in the real world: a realistic view. *Diabet Med*. 2003;20(9): 693-702
- <sup>vii</sup> Wing RR, Marcus MD, Epstein LH, Salata R. Type II diabetic subjects lose less weight than their overweight nondiabetic spouses. *Diabetes Care*. 1987; 10(5):563-566
- <sup>viii</sup> Obesity: guidance on the prevention, identification, assessment and management of overweight and obesity in adults and Children. NICE Guideline December 2006
- <sup>ix</sup> Dixon, JB, O'Brien, PE et al. Adjustable gastric banding and conventional therapy for type 2 diabetes: a randomized controlled trial. *JAMA*. Vol 299 (3) January 2008
- <sup>x</sup> Chapman A, Game P, O'Brien P, Maddern G, Kiroff G, Foster B, Ham J. Executive summary: Laparoscopic adjustable gastric banding for the treatment of obesity: Update and re-appraisal. Australian Safety and Efficacy Register of New Interventional Procedures-Surgical (ASERNIP-S) Report No. 31, Second Edition. Adelaide, South Australia: ASERNIP-S, June 2002
- <sup>xi</sup> Parikh MS, Shen R, Weiner M, Siegel N, Ren CJ. Laparoscopic bariatricsurgery in super-obese patients (BMI>50) is safe and effective: a review of 332 patients. *Obes Surg*. 2005 Jun-Jul;15(6):858-63
- <sup>xii</sup> Chapman AE, Kiroff G, Game P, Foster B, O'Brien P, Ham J, Maddern GJ. Laparoscopic adjustable gastric banding in the treatment of obesity: a systematic literature review. *Surgery* 2004;135:326-351