



LAP-BAND™ shown to improve or lead to remission of type 2 diabetes – it's official!

The LAP-BAND™ has become the first bariatric device in Europe to have official endorsement of its effect on type 2 diabetes in obese patients as a result of surgically induced weight loss

Further to data submissions by Allergan Inc. to TUV SÜD, a European Union notified body responsible for the certification of certain medical devices and implants, the LAP-BAND™ System has received amendments to its official label, which gives specific mention of its proven results in weight loss and the subsequent improvement or remission of type 2 diabetes in obese patients.

This effectively means that the LAP-BAND™ System is now officially endorsed for aiding improvement or remission of type 2 diabetes through weight loss – a world first for any bariatric surgical device.

The new label is a direct consequence of clinical studies published in 2008 by Dr John Dixon of Monash University, Australia, which showed that surgically induced weight loss with the LAP-BAND™ System leads to the improvement or remission of type 2 diabetes in the majority of obese patients recently diagnosed with the condition¹.

In this, the first randomised controlled study comparing surgically induced weight loss with conventional therapy for management of type 2 diabetes in obese participants, Dr Dixon and his team showed that after 2 years the group treated surgically with the LAP-BAND™ System displayed a 5 times higher diabetes remission rate and 4 times greater reduction in HbA1c values compared to the conventional therapy group, confirming the findings of several observational studies.

These compelling results helped the notified body conclude that weight loss with the LAP-BAND™ System is proven to help obese patients achieve improvement or remission of type 2 diabetes. No other bariatric surgical device in Europe is currently endorsed in this way making it a major milestone in the sixteen year history of the LAP-BAND™ System.



How the new LAP-BAND™ System indication reads:

- The LAP-BAND® System is indicated for use in weight reduction for obese patients with a Body Mass Index (BMI) of at least 40 or a BMI of at least 35 with one or more severe co-morbid conditions.
- It is indicated for use only in obese patients who have failed more conservative weight-reduction alternatives, such as supervised diet, exercise and behavior modification programs.
- Patients who elect to have this surgery must make the commitment to accept significant changes in their eating habits for the rest of their lives.
- **Weight loss associated with the LAP-BAND® System has been shown to improve or lead to remission of type 2 diabetes**

LAP-BAND™ System reaches 500,000 milestone

This month, another major milestone was reached, as global sales of the LAP-BAND™ (to date) reached the half a million mark. The number of patients benefiting from LAP-BAND™ surgery has increased dramatically over the past five years as the worldwide obesity epidemic spreads.

Kelvin Tan, European Medical Director for Allergan's Health division said "The LAP-BAND™ System has proved that not only is it a safe and effective means of

achieving sustained weight loss for obese patients, it can also help bring dramatic improvements in a host of related health conditions. In the case of type 2 diabetes, the LAP-BAND™ has already shown to be more effective than conventional therapeutic approaches – both in terms of clinical results and cost². As more healthcare providers begin to understand this, then the growth in LAP-BAND™ surgery only looks set to continue".

For more information or to read these articles in full refer to the following:

1. Dixon JB, O'Brien PE et al Adjustable Gastric Banding and Conventional Therapy for Type 2 Diabetes. A Randomized Controlled Trial; JAMA. 2008;299(3):316-323
2. Keating CL, Dixon JB et al: Cost-Effectiveness of Surgically Induced Weight Loss for the Management of Type 2 Diabetes: Modeled Lifetime Analysis Diabetes Care, 32: 567-574 2009