

LAP-BAND® System History and Development

The LAP-BAND® Adjustable Gastric Banding System is the first U.S Food and Drug Administration (FDA) approved adjustable gastric band for use in weight reduction. To date, this simple reversible surgically implanted device has been successfully used in more than 300,000 procedures worldwide. The LAP-BAND® System is considered safer and less invasive than gastric bypass, as there is no stomach cutting, stapling or intestinal re-routing.^{i,ii}

DEVELOPMENT

The first concept for the gastric band was developed in 1985 by Professor Dag Hallberg, in cooperation with a Swedish medical equipment company. Soon thereafter, Dr. Lubomir Zukmak pioneered the technology in the United States. Clinical trials in select United States centers began in June 1995. The LAP-BAND® System was approved by the FDA in June 2001 for use in weight reduction for severely obese adults with a Body Mass Index (BMI) of 40 or more, or for adults with a BMI of at least 35 plus at least one severe obesity-related health condition, such as Type 2 diabetes, hypertension and asthma.

The name “LAP-BAND” originated from the surgical technique used, laparoscopic, and the name of the implanted medical device, gastric band. The LAP-BAND® System is a silicone ring designed to be placed around the top portion of the patient’s stomach, creating a small gastric pouch and stoma. The inner surface of the band is inflated with sterile saline to create the proper stoma diameter and pouch size. By reducing stomach capacity, the LAP-BAND® System may help achieve long-term weight loss in severely obese adults by creating an earlier feeling of satiety thus limiting or reducing food consumption. The LAP-BAND® System is adjustable, which means that the inflatable band can be tightened or loosened to help the patient achieve a level of satiety while maintaining a healthy diet.

Advantages of the LAP-BAND® System include:

- Less invasive bariatric surgical option^{*i,ii,iii}
- Fewer Risks and Side Effects^{*iii}
- Adjustable
- Reversible
- Effective Long-Term Weight Loss^{iv}

* As compared with gastric bypass

HISTORICAL TIMELINE

➤ 1985

- Professor Dag Hallberg, in cooperation with a Swedish medical equipment company, developed the first concept for the gastric band. His work was followed by Dr. Lubomir Kuzmak, who pioneered the technology in the United States.

➤ 1986

- June marked the first use of open adjustable silicone gastric banding (ASGB).

➤ 1990

- In April, ASGB was used for the first time in Europe. In December, the first FDA-approved ASGB clinical trial started in the United States and the first ASGB workshop was held in Europe.

➤ 1993

- The first laparoscopic banding procedure was performed in Belgium.

➤ 1994

- U.S. based medical device company, Inamed Corporation, created the first workshop for the LAP-BAND® System in Europe.

➤ 1995

- The FDA approved the Investigational Device Exemption (IDE) for a clinical study of the LAP-BAND® System in the United States.

➤ 2001

- The LAP-BAND® System received FDA approval for commercial distribution.

➤ 2007

- To date, the LAP-BAND® System has been implanted in over 300,000 procedures worldwide.

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i 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. (Laparoscopic adjustable gastric banding surgery, like the LAP-BAND® surgery, is associated with a mean short-term mortality rate of around 0.05% compared to 0.50% for Gastric Bypass and 0.31% for Vertical Banded Gastroplasty.)

ii Parikh MS, Shen R, Weiner M, Siegel N, Ren CJ. Laparoscopic bariatric surgery in super-obese patients (BMI>50) is safe and effective: a review of 332 patients. *Obes Surg.* 2005 Jun-Jul;15(6):858-63.

iii 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.

iv O'Brien P, Dixon J, LAP-BAND®: Outcomes and Results, *J of Laparoend & Adv Surg Techniques*, 13(4), 2003, 265-270.