



# New Device Approvals

## LAP-BAND® Adjustable Gastric Banding (LAGB®) System - P000008

*This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.*

Product Name: LAP-BAND® Adjustable Gastric Banding (LAGB®) System  
Manufacturer: BioEnterics Corporation  
Address: 1035 Cindy Lane, Carpinteria, California 93013  
Approval Date: June 5, 2001  
Approval Letter: <http://www.fda.gov/cdrh/pdf/p000008a.pdf>

**What is it?** The LAP-BAND® System is a surgically implanted device used to help a person lose weight. The System consists of a hollow silicone band, tubing, and an access port.

See Illustration

**How does it work?** In a surgical procedure, the band is placed around the upper part of the stomach, creating a small pouch that can hold only a small amount of food. The narrowed opening between the stomach pouch and the rest of the stomach controls how quickly food passes from the pouch to the lower part of the stomach. The system helps the patient eat less by limiting the amount of food that can be eaten at one time and increasing the time it takes for food to be digested.

Depending on the patient's needs, after the device is implanted the narrowed opening between the pouch and the lower part of the stomach can be adjusted in size by inflating or deflating the hollow band. Inflating the band makes the opening smaller, causing food to pass more slowly. Deflating the band makes it wider, causes food to pass more quickly. This adjustment is made by adding or removing fluid inside the hollow band. The doctor does this by injecting or removing the fluid through a small button-like part called the access port. This access port is placed under the skin in a muscle in the chest wall. The port is connected to the band by the tubing.

**When is it used?** The system is used for weight loss in *severely* obese adults who have been obese for at least five years and for whom non-surgical weight loss methods have not been successful. They must be willing to make major changes in their eating habits and lifestyle. Patients must have a Body Mass Index (BMI) of at least 40, a BMI of at least 35 with one or more severe morbid (unhealthy) conditions, or be at least 100 pounds over their estimated ideal weight.

**What will it accomplish?** It may help the patient lose weight. In the U.S. study, the average weight loss was 36% of a patient's excess weight three years after the device was implanted. More than half of the patients lost at least 25% of their excess weight; some patients lost over 75%, but some lost no weight.

**What are the risks?** Most patients experienced at least one side effect. Common side effects include

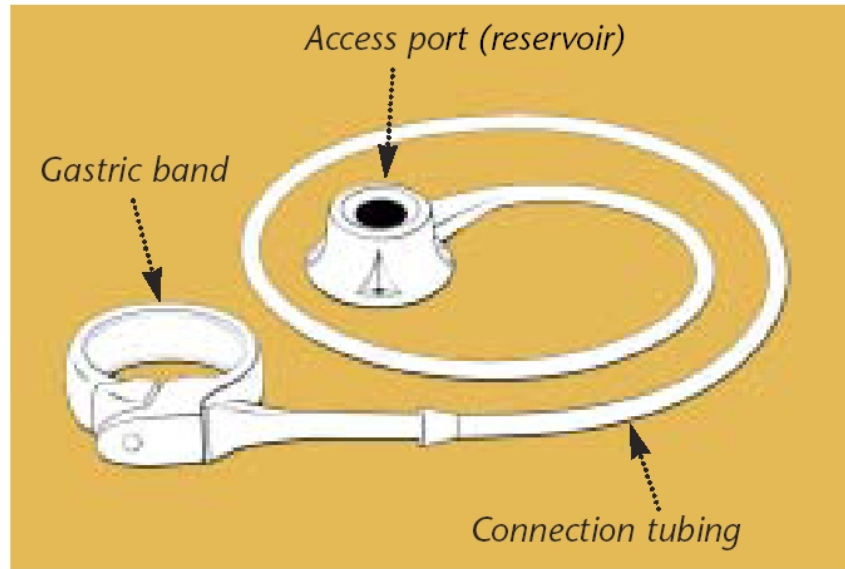
nausea and vomiting, heartburn, abdominal pain, and slippage of the band. The most serious side effects required either another operation or hospitalization.

**When should it not be used?** It should not be used for people who are poor candidates for surgery, have certain stomach or intestinal disorders, have an infection, have to take aspirin frequently, or are addicted to alcohol or drugs. It should not be used on patients who are not able or willing to follow the rules for eating and exercise that are recommended by the doctor after surgery.

**Additional information:** The SSED and Labeling will be available at:

<http://www.fda.gov/cdrh/pdf/p000008.html>

*(Updated 6/6/2001)*



*The LAP-BAND Adjustable Gastric Banding System*