

FDA approves stomach-filling balloon for weight loss

July 28 2015, byMatthew Perrone

Federal health regulators on Tuesday approved an inflatable medical balloon that aids weight loss by filling up space in the stomach.

The Food and Drug Administration cleared Reshape Medical's balloon as another option for millions of obese Americans who have been unable to lose weight via more traditional methods.

The balloon is inserted into the stomach using an endoscope and then filled with saline solution. Patients are sedated during the procedure, which takes less than 30 minutes, according to an FDA release.

The FDA previously approved another balloon device for weight loss but it was withdrawn in 1992 due to a safety issue in which the balloon could rupture and block patients' arteries.

"The new device aims to address the design failings of the earlier device," said FDA spokeswoman Deborah Kotz, in an emailed statement.

More than a third of U.S. adults are obese—defined as having a body mass index of 30 or higher—and that's been the case since the middle of the last decade. Weight loss surgery is recommended for those with a BMI of 40 or those with a BMI of 35 who have other risk factors for heart disease such as diabetes or high blood pressure. A 5-foot-9 person would be obese at 203 pounds.

The balloon approved Tuesday is approved for obese adults with a BMI between 30 and 40 who have at least one complicating condition and have been unable to lose weight through diet and exercise alone.

Dr. Ninh Nguyen, past president of the American Society for Metabolic and Bariatric Surgery, said in a company release that the procedure "opens up a new opportunity" for patients who do not qualify for weight loss surgery.

In company trials, patients treated with the balloon lost about 7 percent of their total body weight over six months, compared with 3.3 percent weight loss in patients who didn't get the balloon. But six months after the devices' removal, patients in the balloon group regained more than two-thirds of the weight they had lost.

The effect seen with the balloon is smaller than that associated with gastric banding, a stomach-shrinking technique that limits food intake, but can cause esophagus irritation, infection and vomiting, in some cases. Patients can lose as much as 17 percent of their total body weight with banding devices, such as the LAP-Band, although about 20 percent of patients regain nearly all the weight within three years.

More effective is gastric bypass surgery, a permanent procedure in which a small pouch is stapled off from the rest of the stomach and connected to the small intestine. Studies of that technique show patients typically lose about 30 percent of their weight.

Reshape Medical said Tuesday its balloon system will initially be available through certain providers who are trained in performing the procedure. The company did not disclose the cost, saying it would vary by region.

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