U.S. Food and Drug Administration
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FDA News Release

FDA approves non-surgical temporary balloon device to treat obesity

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Release

Español (/NewsEvents/Newsroom/ComunicadosdePrensa/ucm456590.htm)

The U.S. Food and Drug Administration today approved a new balloon device to treat obesity without the need for invasive surgery. The ReShape Integrated Dual Balloon System (ReShape Dual Balloon) is intended to facilitate weight loss in obese adult patients. The device likely works by occupying space in the stomach, which may trigger feelings of fullness, or by other mechanisms that are not yet understood.

The ReShape Dual Balloon device is delivered into the stomach via the mouth through a minimally invasive endoscopic procedure. The outpatient procedure usually takes less than 30 minutes while a patient is under mild sedation. Once in place, the balloon device is inflated with a sterile solution, which takes up room in the stomach.

The device does not change or alter the stomach's natural anatomy. Patients are advised to follow a medically supervised diet and exercise plan to augment their weight loss efforts while using the ReShape Dual Balloon and to maintain their weight loss following its removal. It is meant to be temporary and should be removed six months after it is inserted.

"For those with obesity, significant weight loss and maintenance of that weight loss often requires a combination of solutions including efforts to improve diet and exercise habits," said William Maisel, M.D., M.P.H., acting director of the Office of Device Evaluation at the FDA's Center for Devices and Radiological Health. "This new balloon device provides doctors and patients with a new non-surgical option that can be quickly implanted, is non-permanent, and can be easily removed."

The ReShape Dual Balloon is indicated for weight reduction in **obese adult patients (http://www.cdc.gov/obesity/adult/index.html)** with a **body mass index (http://www.cdc.gov/healthyweight/assessing/bmi/)** (BMI) of 30 to 40 kg/m^2. The device is limited to patients with one or more obesity-related conditions such as high blood pressure, high cholesterol, and diabetes. It is intended for patients who have failed previous attempts at weight loss through diet and exercise alone.

There are currently three other FDA-approved devices to treat morbid obesity: the **Allergan LAP-Band (http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/Gastroenterology-UrologyDevicesPanel/UCM302772.pdf)** the **Ethicon Endo-Surgery Realize Adjustable Gastric Band (http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/Gastroenterology-UrologyDevicesPanel/UCM302775.pdf)** and the **Maestro Rechargeable System (http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130019b.pdf)**.

The ReShape Dual Balloon was studied in a clinical trial with 326 obese participants aged 22 to 60 (with a BMI of 30 kg/m^2 to 40 kg/m^2) who had at least one obesity-related health condition. In the study, 187 individuals randomly selected to receive the ReShape Dual Balloon lost 14.3 pounds on average (6.8 percent of their total body weight) when the device was removed at six months, while the control group (who underwent an endoscopic procedure but were not given the device) lost an average of 7.2 pounds (3.3 percent of their total body weight).

Six months following the device removal, patients treated with the ReShape Dual Balloon device kept off an average of 9.9 pounds of the 14.3 pounds they lost.

Potential side effects for the procedure include headache, muscle pain, and nausea from the sedation and procedure; in rare cases, severe allergic reaction, heart attack, esophageal tear, infection, and breathing difficulties can occur. Once the device is placed in the stomach, patients may experience vomiting, nausea, abdominal pain, gastric ulcers, and feelings of indigestion.

This device should not be used in patients who have had previous gastrointestinal or bariatric surgery or who have been diagnosed with inflammatory intestinal or bowel disease, large hiatal hernia, symptoms of delayed gastric emptying or active H. Pylori infection; those who are pregnant or use aspirin daily should also avoid the device.The ReShape Dual Balloon is manufactured by ReShape Medical Inc., in San Clemente, Calif.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Related Information

- FDA: Medical Devices (/MedicalDevices/default.htm)
- FDA Approved Obesity Treatment Devices (/MedicalDevices/ProductsandMedicalProcedures/ObesityDevices/default.htm)
- Premarket Approval (PMA) (/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.htm)
- May 10-11, 2012: Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee (Topic: Obesity Devices) (/AdvisoryCommittees/Calendar/ucm297473.htm)
- More information on ReShape (/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm456293.htm)

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