FDA issues warning about balloon obesity treatments

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(HealthDay)—Fluid-filled balloons placed in the stomach to treat obesity

have been linked to serious complications, the U.S. Food and Drug Administration reports.

The balloons treat obesity by taking up space in a patient's stomach, and are used in conjunction with diet and exercise. Two types of fluid-filled balloon systems—the ReShape Integrated Dual Balloon System and the Orbera Intragastric Balloon System—were approved by the FDA in 2015.

But in a recent warning sent to health care providers, the FDA said it has received multiple reports of complications associated with the two balloon systems.

One type of problem involved the balloons over-inflating with air or with more fluid in patients' stomachs. This led to the premature removal of the balloons.

The second type of problem is development of acute pancreatitis. This complication also led to the removal of the balloons. This may occur due to compression of digestive system structures, the FDA said.

The FDA letter recommends that health care providers "closely monitor patients with these devices for these adverse events, and to submit reports to help us better understand any complications from the use of these obesity treatment devices."

The agency said it is working with the manufacturers to better understand the problems caused by the fluid-filled balloon systems. The FDA said it will provide more information as the investigation continues.

No problems have been reported with another type of balloon system used to treat obesity—the Obalon system—which uses only air, the FDA

said.

More information: The U.S. National Heart, Lung, and Blood Institute has more on obesity treatment.