

Company claims 'world's first procedureless weight loss device' offers a new treatment option for overweight and obese individuals

ALLURION Technologies has announced that its Elipse Gastric Balloon has received a CE mark allowing sale of the product in the European Union, the company's first regulatory approval. Elipse is Allurion's flagship product and, the company claims, is the world's first procedureless gastric balloon. The device will initially be available in select leading weight loss centers in France, Italy and the United Kingdom. Elipse is not yet approved by the FDA and is not available for sale in the US.

Elipse is made of thin, flexible polymer film and is delivered in a swallowable capsule, eliminating the need for surgery, endoscopy or anaesthesia. Once the patient swallows a capsule, it quickly dissolves in the stomach to reveal a deflated gastric balloon inside. With a thin catheter attached to the device, but long enough to remain outside the patient's mouth and a physician fills the balloon with fluid (550mL). The catheter is then removed, while the balloon remains in the stomach for four months. At that point, a valve designed

to open on its own, allows the balloon to empty and be excreted naturally from the body, eliminating the need for endoscopy or another procedure.

"Excess weight often has a profound impact on health and quality of life including work, relationships and self-perception," said Dr Shantanu Gaur, Allurion's Co-Founder and Chief Scientific Officer. "Our procedureless gastric balloon offers a simple, safe and effective alternative. Elipse is a new way

for overweight and obese individuals to take action."

Allurion has studied Elipse in individuals with a BMI27-40 to assess its safety and its effects on body weight, metabolic parameters and quality of life. As reported previously by *Bariatric News* (<http://www.bariatricnews.net/?q=news/112199/elipse-balloon-pill-posts-positive-results>), interim results from a clinical study in 34 individuals presented at ObesityWeek in

November 2015, reported an average weight loss of 10 kilograms (22lbs), with participants losing 37 percent of their excess weight and eight centimeters off their waist circumference over the four month treatment period. Participants also saw improvements in their triglycerides, hemoglobin A1c (HbA1c) and all aspects of quality of life. All balloons were safely and naturally excreted.

"Following six years of develop-

ment, we are very excited to enter the next phase of our company's growth," said Jonathan Wecker, Allurion Technologies' Chief Executive Officer. "I am extremely proud of our team and thankful for the support of the many physicians and allied caregivers that have helped make Elipse a reality. Following initial release in Europe, we expect to offer Elipse in the Middle East and beyond in the months and years to come."

