

TITLE: Overview of Anti-Obesity Medical Devices

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ABSTRACT

Anti-obesity medical devices represent a heterogeneous family of devices in terms of presentation, usage/administration, mechanism of action, effectiveness, safety, regulation, availability, and cost. They offer an attractive approach in the management of obesity. Compared to bariatric surgery, they have the advantage of being less invasive, easier to perform, and reversible. Anti-obesity medical devices act mechanically without receptors, systemic absorption, or specific metabolism. Because there is no systemic absorption, there are no side effects related to the impact of medical devices on different organs through the bloodstream. Several anti-obesity medical devices have been approved/cleared in the USA, in Europe, and in other countries. Medical devices cause weight loss through different mechanisms such as decrease in food intake or decrease in available/absorbed nutrients. There are three regulatory classes of medical devices: Class I (low risk), Class II (moderate risk), and Class III (high risk). Based on the expected weight loss, the Center for Devices and Radiological Health of the Food and Drug Administration in charge of approval/clearance of anti-obesity medical devices in the USA categorizes anti-obesity medical devices as weight-loss devices or weight-management devices. The weight-loss devices include gastric band devices [e.g., Lap-Band® Adjustable Gastric Banding (LAGB®)], gastric spaceoccupying devices [e.g., Orbera® Intragastric Balloon System, Obalon® Balloon System, and TransPyloric Shuttle® (TPS®)], and gastric emptying devices (e.g., AspireAssist®). The weightmanagement devices include oral space-occupying devices (e.g., SmartByte Device) and gastric space-occupying devices (e.g., Plenity®). The use of anti-obesity medical devices should always be in conjunction with lifestyle recommendations. Considering the large market size of obesity treatment and the small percentage of subjects treated with anti-obesity drugs or bariatric surgery, anti-obesity medical devices can play an important role in the management of obesity.





BIOGRAPHY

Hassan M. Heshmati, Medical Doctor, Endocrinologist, has 46 years of experience in clinical research in both Academia (University-Affiliated Hospitals, Paris, France and Mayo Foundation, Rochester, MN, USA) and Pharmaceutical/Biotech Companies (Sanofi, Malvern, PA, USA, Essentialis, Carlsbad, CA, USA, and Gelesis, Boston, MA, USA). His research activity has been related to pituitary tumor, hyperthyroidism, thyroid cancer, osteoporosis, obesity, and diabetes. He has extensive knowledge in the development of anti-obesity products. He is the author of 310 abstracts, chapters, and articles related to Endocrinology and Metabolism. Currently, he is Consultant at Endocrinology Metabolism Consulting, LLC, Anthem, AZ, USA.

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