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A NOVEL ENDOSCOPIC REVERSIBLE BARIATRIC DEVICE: ANIMAL RESULTS AND INITIAL CLINICAL EXPERIENCE

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Background: In the US alone there are nearly 100 million overweight, obese and morbidly obese individuals. Existing bariatric surgical therapies address a very small percentage of these individuals. Of the 23 million morbidly obese patients in the United States, approximately 1% undergoes conventional weight loss surgery. Diet, exercise, and medications produce minimal weight loss at best and most regain or exceed baseline weight within 5 years. The typical result is decreased metabolism, constant hunger, depression which results in a high failure rate. Additionally many bariatric patients experience weight regain over time due to difficulty in achieving continued satiety. As a result there is a critical need for a non-invasive, reversible, safe device that can deliver effective satiety and result in weight loss.

Description: The Full Sense™ is a reversible bariatric device, deployed and removed endoscopically. It incorporates an esophageal component and a gastric disk connected by a strut. It is designed to induce satiety and fullness in the absence of food by placing pressure on the distal esophagus and cardia of the stomach.

Clinical Animal Results: In four separate studies, animals lost approximately 23% of their body weight whereas controls gained 3% in 28 days.

Clinical Human Results: The device was endoscopically placed in 3 female patients (mean BMI of 44.0, mean age of 38 years), and secured via laparoscopic assistance. Patients lost an average of 28% of their excess body weight in 46 days. The devices were removed endoscopically. There was no device migration, no ulcers and no compromise of the GE junction. Inflammation, which was present at the time of explantation was confirmed resolved at three week post-operative follow up endoscopy. The patients were required to record their satiety levels daily using a standardized satiety scale. All patients recorded increased satiety with The Full Sense™ Device in place than after removal.

Conclusions: The Full Sense™ Device has been shown to be an effective endoscopically placed and removable bariatric treatment in pre-clinical and clinical studies.