Surgeons Use Incisionless Operating Platform to Reduce Pouch, Stoma Size In Gastric Bypass Patients

Data shows expandable tissue anchors remain in place up to 12 months

SAN CLEMENTE, Calif., June 29 /PRNewswire/ -- New data show that surgeons can use USGI Medical Inc.'s (USGI) Incisionless Operating Platform™ (IOP) to durably reduce the size of the stomach pouch and stoma in Roux-en-Y Gastric Bypass (RYGB) patients who are regaining weight because this portion of their anatomy has stretched since their original surgery.

On Friday, June 26 at the American Society of Metabolic and Bariatric Surgeons (ASMBS) Annual Meeting near Dallas, University of California, San Diego (UCSD) Medical Center surgeon Santiago Horgan, M.D. presented outcomes from 116 patients who underwent this incisionless procedure to reduce the size of their pouch and stoma.

"We believe this is the first data to confirm 12-month durability for gastric folds created without incisions," said Dr. Horgan, director of UCSD's Center for the Future of Surgery and Center for the Treatment of Obesity.

"Invasive procedures to restore the anatomy to the original post-surgery proportions are too complicated for many patients. Surgeons have tried to perform restorative procedures through the mouth using other types of endoscopic instruments, however GI tissue is extremely resistant to change and it's been difficult to show long-term durability of procedures utilizing endoscopic sutures or staples. USGI's Expandable Tissue Anchors have allowed us to achieve a desired amount of durable reduction in the pouch and stoma size without any significant adverse events, filling a significant unmet medical need in this patient population."

To perform a Restorative Obesity Surgery, Endolumenally (ROSE), surgeons used USGI's IOP to grasp tissue and deploy Expandable Tissue Anchors to create multiple, circumferential tissue folds around the stoma and inside the pouch.

The procedure is performed entirely through the patient's mouth. An endoscope provides visualization. Surgeons were able to place tissue folds in 112 of 116 (97 patients. On average, surgeons placed six Expandable Tissue Anchor pairs in each of these

112 patients and reduced their mean stoma diameter by 50% and pouch length by 44 percent.

Dr. Horgan reported that twelve-month post-op endoscopies performed on 19

patients to date confirmed the durability of the procedure: the tissue anchors remained and durable tissue folds were present. There were no significant complications associated with the procedure and most patients reported no or minimal pain.

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