

## Removal of Colon Polyps Just Got Easier Thanks to the GripTract-GI™ Endoscopic Tissue Manipulator

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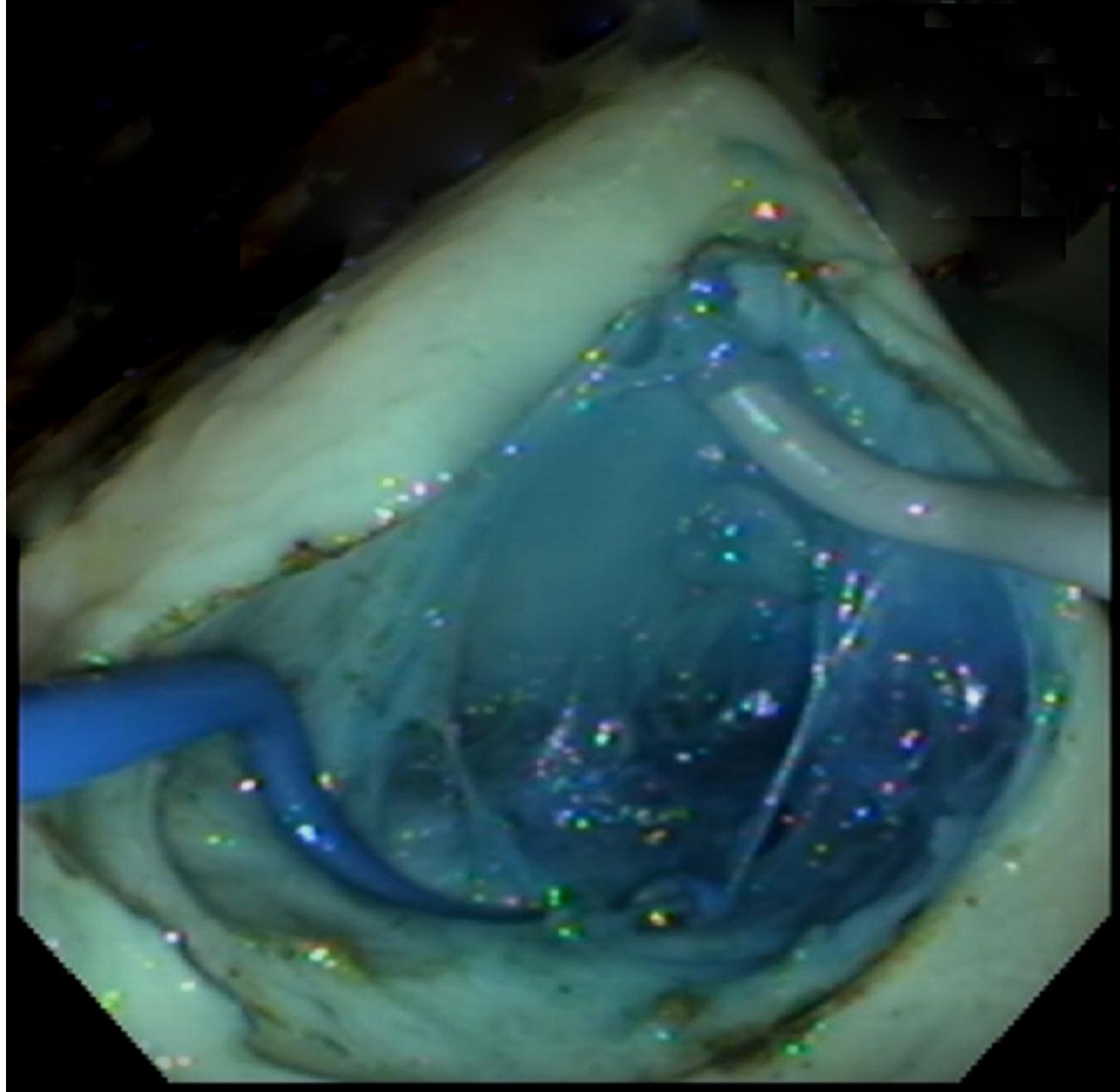
Actuated Medical, a woman-owned medical device company in Bellefonte, Pennsylvania, has achieved another milestone. The GripTract-GI™ endoscopic tissue manipulator (GripTract)—a patented accessory for the tip of an endoscope—recently received FDA 510(k) marketing clearance with the support of the NIH Small Business Innovation Research (SBIR) program. GripTract, along with the company's other successful products—NeuralGlider inserter and the TubeClear system—is a testament to Actuated Medical's leadership in product innovation.

Of the 7 million endoscopic polyp removal procedures performed annually in the U.S., nearly 15% are complex, but there is a lack of affordable accessories than can aid in safely removing larger polyps. GripTract, a lower-cost accessory for endoscopes, has the potential to reduce training time, procedure time, and complications, ultimately delivering better treatment.

GripTract, an invaluable addition to endoscopic investigations and interventions in the gastrointestinal tract, is a single-use cap equipped with movable fingers that extend from the end of the endoscope. The GripTract Fingers can be used to manipulate tissue during endoscopic procedures for better visualization, to move the cutting tool without moving the endoscope, and to stabilize the endoscope while cutting tissue. Dr. Maureen L. Mulvihill, CEO and co-founder of Actuated Medical, explains that the company's scientists and engineers sought to move tissue in controlled ways to improve the surgeon's view during endoscopic procedures.

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The Small Business Program at the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) provided essential support. According to Dr. Mulvihill, “SBIR funding has enabled us to investigate the clinical need, work with doctors to develop the technology, and then has allowed us to do the required testing that the FDA requires for a 510(k). In addition, the SBIR funding is helping to support clinical studies at Cleveland Clinic and Columbia University.”



As part of those clinical studies, the GripTract SBIR Phase IIB project expands the GripTract product line to assist in upper GI endoscopy procedures. The motivation for this expansion stems from the challenges clinicians face in safely removing large and complicated polyps, particularly those prone to recurrence and malignancy.

GripTract has the promise of advancing diagnosis and endoscopic treatment far beyond what can be achieved at present. Now that GripTract can be sold within the U.S., the product is well-placed to achieve the company's goal of licensing the technology to a strategic partner that can facilitate much broader usage by surgeons.

9 August, 2024